DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 864, 866, 880, 882, 884, 886, 888, 890, and 892

[DOCKET NO. 98N–0009]

Medical Devices; Exemption From Premarket Notification and Reserved Devices; Class I

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its classification regulations to designate class I devices that are exempt from the premarket notification requirements, subject to certain limitations, and to designate those class I devices that remain subject to premarket notification requirements under the new statutory criteria for premarket notification requirements. The devices FDA is designating as exempt do not include class I devices that have been previously exempted by regulation from the premarket notification requirements. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (SMDA), and the FDA Modernization Act of 1997 (FDAMA). FDA is taking this action in order to implement a requirement of FDAMA, Elsewhere in this issue of the Federal Register, FDA is announcing that it is withdrawing proposed rules to revoke existing exemptions from premarket notification for two devices.

DATES: This regulation is effective February 14, 2000.


SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the act (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the 1976 amendments (Public Law 94–295), as amended by the SMDA (Public Law 101–629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to ensure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device, or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, part 807 (21 CFR part 807), require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is substantially equivalent within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval. Unless exempted from premarket notification requirements, persons may not market a new device under section 510(k) of the act, unless they receive a substantial equivalence order from FDA or an order reclassifying the device into class I or class II, under section 513(f) of the act. On November 21, 1977, the President signed FDAMA into law (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(l) to the act. Under section 206 of FDAMA, new section 510(l) of the act became effective on February 19, 1998. New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. This document refers to devices that FDA believes meet these criteria as “reserved.” FDA has evaluated all class I devices to determine which device types should be subject to premarket notification requirements.

In developing the list of reserved devices, the agency considered its experience in reviewing premarket notifications for these device types, focusing on the risk inherent with the device and/or the disease being treated or diagnosed. FDA believes that the devices listed as reserved are intended for a use that is of substantial importance in preventing impairment of human health or present a potential unreasonable risk of illness or injury.

II. Limitations on Exemptions

FDA believes that the generic types of class I devices listed herein, in addition to a vast majority of class I devices previously exempted, should be exempt from the premarket notification requirements under section 510(l) of the act. FDA further believes, however, that these generic device categories should be exempt only to the extent that they have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices (IVD’s), only to the extent that they misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. FDA believes that certain changes to devices within a generic device type that is generally exempt may make the device intended for a use that is of substantial importance in preventing impairment of human health or may make the device present a potential unreasonable risk of illness or injury. Accordingly, devices changed in this manner would fall within the reserved criteria under section 510(l) of the act and would require premarket notification.

FDA believes that devices that have different intended uses than legally marketed devices in that generic device type present a potential unreasonable risk of illness or injury because their safety and effectiveness characteristics
are unknown. Moreover, FDA believes that IVD’s are intended for a use that is of substantial importance in preventing impairment of human health or present a potential unreasonable risk of illness or injury, if misdiagnosis, as a result of using the device, could result in high morbidity or mortality.

Accordingly, because FDA believes that devices incorporating the characteristics described above fit within the reserved criteria under section 510(l) of the act, FDA considers any class I device to be subject to premarket notification requirements if the device: (1) Has an intended use that is different from the intended use of a legally marketed device in that generic type of device (e.g., the device is intended for a different medical purpose, or the device is intended for lay use instead of use by health care professionals); or (2) operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type of device (e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an IVD detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization or amplification technology rather than culture or immunooassay technology); or (3) is an in vitro device that is intended: (a) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices; (b) for use in screening or diagnosis of familial and acquired genetic disorders, including inborn errors of metabolism; (c) for measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy; (d) to assess the risk of cardiovascular diseases; (e) for use in diabetes management; (f) to identify or infer the identity of a microorganism directly from clinical material; (g) for detection of antibodies to microorganisms other than immunoglobulin G (IgG) and IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma; (h) for noninvasive testing as defined in § 812.3(k) (21 CFR 812.3(k)); and (9) for near patient testing (point of care). FDA is revising §§ 862.9, 864.9, and 866.9 (21 CFR 862.9, 864.9, and 866.9) these revised limitations on exemptions for IVD’s. FDA believes that these limitations, for the reasons described previously, are appropriate for IVD’s.

FDA is also amending all current limitations on exemptions sections (21 CFR 862.9, 864.9, 866.9, 868.9, 870.9, 872.9, 874.9, 876.9, 878.9, 880.9, 882.9, 884.9, 886.9, 888.9, 890.9, and 892.9) in two ways. First, the limitations language clarifies that these limitations apply to class II, as well as class I devices. On January 21, 1998 (63 FR 3142), FDA published a list of exempted class II devices, subject to certain limitations. Under section 510(m)(1) of the act, as added by FDAMA, FDA was provided the authority to exempt these class II devices from premarket notification upon issuance of a notice. FDA codified these exemptions, including the limitations described in the January 21, 1998. Federal Register notice, by issuance of a final rule on November 3, 1998 (63 FR 59222).

The limitations language in this document for class I devices is identical to those limitations for class II devices that became effective January 21, 1998. Accordingly, the limitations sections state that the scope of these limitations apply to class II, as well as class I devices.

Second, FDA is amending the limitations language to state that premarket notifications must be submitted for class I exempt devices if the intended use is different than the “legally marketed devices in that generic type.” Currently, the limitations in each classification regulation (e.g., §§ 862.9, 864.9, etc.) state that manufacturers must submit premarket notifications for class I exempt devices when “[t]he device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent;”’. Devices that have an intended use that differs from any legally marketed device are not exempt because those devices present a potential unreasonable risk of illness or injury because their safety and effectiveness characteristics are unknown. Manufacturers of such devices must submit a premarket notification and the agency will determine if they are substantially equivalent to other legally marketed devices in that generic device type.

In addition to the general limitations on exemptions applicable to all class I devices that are described previously, certain devices within a generic class also remain subject to the premarket notification requirements because they either are intended for a use that is of substantial importance in preventing impairment of human health or they present a potential unreasonable risk of illness or injury. For example, elsewhere in this document, FDA states that liquid bandages are generally exempt from the premarket notification requirements, but a subcategory of those devices, those intended for treatment of burns and other open wounds, remains subject to the premarket notification requirements. FDA believes that liquid bandages intended for burns and other open wounds should remain subject to this requirement because they are of substantial importance in preventing impairment of human health by helping to prevent infections.

FDA also advises that an exemption from the requirement of premarket notification does not mean that the device is exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation.

The limitations in each classification regulation apply to premarket notification exemptions for each class of device classified in each section. In addition to mentioning the limitations generally in each classification regulation, FDA specifically states in the classification sections for each generic device that is newly exempted under section 510(l) of the act that the exemptions are subject to limitations. For example, with this regulation § 862.1200 states that the corticosterone test system “is exempt from the premarket notification requirements in subpart E of part 807 of this chapter subject to § 862.9. ” (Emphasis added.) FDA is adding this language specifically referring to the limitations language for clarity and convenience.

Individual device classification sections that have been codified previously that are exempt from premarket notification requirements, subject to limitations, do not specifically refer to the general limitations section. For these classifications, FDA intends to codify language in the near future that will mention the limitations sections in each device classification.

III. Analysis of Comments

In the Federal Register of February 2, 1998 (63 FR 5387), FDA published a list of devices it considered reserved and that require premarket notification and a list of devices it believed met the exemption criteria in FDAMA. FDA invited comments on the February 2, 1998, notice.

In the Federal Register of November 12, 1998 (63 FR 63222), after reviewing the comments submitted on the February 2, 1998, Federal Register
notice, FDA proposed to designate which devices require premarket notification, and which are exempt, subject to limitations, under notice and comment rulemaking proceedings under new section 510(l) of the act. FDA received four comments in response to the proposed rule. The following is FDA’s response to those comments.

1. One comment in regard to unscented menstrual pads (§ 884.5435) (21 CFR 884.5435) stated that: (1) Interlabial pads do not contact vaginal tissue; (2) interlabial pads should not be grouped with reusable menstrual pads in the regulation because they have different risks; and (3) the term “intralabial” is not accurate and the correct nomenclature is “interlabial.”

Both interlabial pads and reusable pads are types of unscented menstrual pads that meet the reserved criteria, and, therefore, must meet the premarket notification requirements. Other types of unscented menstrual pads are exempt. Although FDA agrees that interlabial pads do not contact vaginal tissue and that interlabial pads present different risks than reusable menstrual pads, both types of pads still meet the reserved criteria. FDA did not group these types of pads as reserved devices because they had the same risks but has determined both need to undergo premarket review based on their risks independently. FDA agrees that the term the term “intralabial” is more appropriate than the term “intralabial” and is using the term “intralabial” in the final rule and § 884.5435.

2. Another comment requested clarification of the scope of the classification and exemption of the blood bank centrifuge for in vitro diagnostic use (§ 864.9275 (21 CFR 864.9275)). More specifically, the comment asked whether centrifuges used to separate whole blood into its component parts for eventual transfusion to patients are exempt from premarket notification. Section 864.9275 applies to the small tabletop centrifuges used to spin down test tubes of blood samples used in immunohematology tests. This classification does not include a centrifuge used to separate or prepare blood components for transfusion, which is classified in class II as an autotransfusion apparatus (21 CFR 888.63) and is subject to premarket notification requirements.

Section 864.9275 applies to the small tabletop centrifuges used to spin down test tubes of blood samples used in immunohematology tests. This classification does not include a centrifuge used to separate or prepare blood components for transfusion, which is classified in class II as an autotransfusion apparatus (21 CFR 888.63) and is subject to premarket notification requirements. FDA has reviewed the devices that fall under this regulation and agrees that many of the devices do not involve electrical connections to the patient. On August 9, 1999 (64 FR 43114), FDA published a proposed rule to reclassify three devices into class II in order to make them subject to the performance standard for electrode lead wires and patient cables. These three devices are: (1) Cardiopulmonary bypass accessory equipment that involves an electrical connection to the patient, (2) the goniometer device, and (3) the electrode cable. Under this proposal, cardiopulmonary bypass accessory equipment that does not involve an electrical connection to the patient would remain in class I and would be exempt from the premarket notification requirements. Section 864.9275 states that specific indication can be marketed.

FDA has reviewed the devices that fall under this regulation and agrees that many of the devices do not involve electrical connections to the patient. On August 9, 1999 (64 FR 43114), FDA published a proposed rule to reclassify three devices into class II in order to make them subject to the performance standard for electrode lead wires and patient cables. These three devices are: (1) Cardiopulmonary bypass accessory equipment that involves an electrical connection to the patient, (2) the goniometer device, and (3) the electrode cable. Under this proposal, cardiopulmonary bypass accessory equipment that does not involve an electrical connection to the patient would remain in class I and would be exempt from the premarket notification requirements. Section 864.9275 states that specific indication can be marketed.

The proposed rule, however, did not include the keratoscope with computer software under those devices FDA proposed to codify as exempt. Subsequent to the issuance of the proposed rule, FDA received an inquiry concerning the exemption status of this device. Upon consideration, FDA does not believe that the keratoscope with computer software is intended for a use that is of substantial importance in preventing impairment of human health or that it presents a potential unreasonable risk of illness or injury and therefore it is exempt from the premarket notification requirements.

6. FDA, on its own initiative, has made some minor changes in the sections of each classification, which describe the limitations to exemptions from section 510(l) of the act. In these sections, FDA lists certain intended uses or changes that will preclude a device
from falling within an exemption that is otherwise applicable to a generic class of devices.

In the final rule, FDA made some nonsubstantive changes in the introductory paragraph that clarify FDA’s reasons for the types of limitations listed. In proposed sections of each classification regulation, FDA explained that it listed the limitations because those types of changes were unforeseeable, and, therefore could significantly affect safety and effectiveness. The final rule clarifies that FDA also listed certain types of limitations because any misdiagnosis using devices for the listed intended uses may be associated with high morbidity or mortality.

In addition, FDA has made minor changes in describing two of the intended uses of in vitro devices that would require a premarket notification. Proposed limitations in paragraph (c)(2) stated that premarket notifications must be submitted when a device is an in vitro device that is intended for use in “screening or diagnosis of familial and acquired genetic disorders, including inborn errors of metabolism.” The proposed rule could be interpreted to require premarket notification for in vitro devices intended for detection of antibodies to microorganisms other than immunoglobulin G (IgG) and IgG assays when the results are not qualitative * * *.” The proposed rule could be interpreted to require premarket notification unless the device were intended for detection of both IgG and IgG assays. FDA is amending the final rule in the limitation in paragraph (c)(7) by replacing the word “and” with “or” to indicate that if an exempt in vitro device is intended to detect antibodies to either IgG or IgG assays, the device will remain exempt.

7. FDA, on its own initiative, has added language clarifying the description of exempted devices in § 880.5090 Liquid bandage (21 CFR 880.5090), § 886.4070 Powered corneal burr (21 CFR 886.4070), and § 886.4750 Ophthalmic eye shield (21 CFR 886.4750). The proposed classification descriptions state that the devices were exempt from premarket notification requirements when used for certain intended uses. FDA has added language to clarify that the exemption applies only when the device is used exclusively for the intended uses stated in the classification descriptions.

8. Also, on its own initiative, FDA is revising the description of the exempted device, rubber dam, in 21 CFR 872.6300(a) to clarify that this device does not include a rubber dam, which is intended for prevention of sexually transmitted diseases during oral sex. Such a device is classified as a condom in 21 CFR 884.5300.

IV. Designation of Devices

The following devices are devices that FDA believes meet the reserved criteria in section 206 of FDAMA and, therefore, FDA is codifying the determination that they remain subject to premarket notification under new section 510(l) of the act:

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>Name of Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>862.1065</td>
<td>Ammonia test system</td>
</tr>
<tr>
<td>862.1113</td>
<td>Bilirubin (total and unbound) in the neonate test system</td>
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<tr>
<td>862.1310</td>
<td>Galactose test system</td>
</tr>
<tr>
<td>862.1410</td>
<td>Iron (non-heme) test system</td>
</tr>
<tr>
<td>862.1415</td>
<td>Iron-binding capacity test system</td>
</tr>
<tr>
<td>862.1495</td>
<td>Magnesium test system</td>
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<tr>
<td>862.1580</td>
<td>Phosphorous (inorganic) test system</td>
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<tr>
<td>862.1660</td>
<td>Quality control material (assayed and unassayed) ¹</td>
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<tr>
<td>862.1680</td>
<td>Testosterone test system</td>
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<tr>
<td>862.1730</td>
<td>Free tyrosine test system</td>
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<td>862.1775</td>
<td>Uric acid test system</td>
</tr>
<tr>
<td>862.2050</td>
<td>Breath-alcohol test system</td>
</tr>
<tr>
<td>862.3110</td>
<td>Antimony test system</td>
</tr>
<tr>
<td>862.3120</td>
<td>Arsenic test system</td>
</tr>
<tr>
<td>862.3220</td>
<td>Carbon monoxide test system</td>
</tr>
<tr>
<td>862.3240</td>
<td>Cholinesterase test system</td>
</tr>
<tr>
<td>862.3280</td>
<td>Clinical toxicology control material (assayed and unassayed) ¹</td>
</tr>
<tr>
<td>862.3600</td>
<td>Mercury test system</td>
</tr>
<tr>
<td>862.3750</td>
<td>Quinine test system</td>
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<td>862.3850</td>
<td>Sulfonamide test system</td>
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<tr>
<td>864.7040</td>
<td>Adenosine triphosphate release assay</td>
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<td>864.8950</td>
<td>Russell viper venom reagent</td>
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<tr>
<td>864.9050</td>
<td>Blood bank supplies</td>
</tr>
<tr>
<td>864.9125</td>
<td>Vacuum-assisted blood collection system ²</td>
</tr>
<tr>
<td>864.9195</td>
<td>Blood mixing devices and blood weighing devices ²</td>
</tr>
</tbody>
</table>
### TABLE 1—DESIGNATIONS OF RESERVED CLASS I DEVICES—Continued

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>Name of Device</th>
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<tbody>
<tr>
<td>866.2390</td>
<td>Transport culture medium</td>
</tr>
<tr>
<td>866.2560</td>
<td>Microbial growth monitor(^3)</td>
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<tr>
<td>866.2850</td>
<td>Automated zone reader</td>
</tr>
<tr>
<td>866.2900</td>
<td>Microbiological specimen collection and transport device</td>
</tr>
<tr>
<td>866.3110</td>
<td>Campylobacter fetus serological reagents</td>
</tr>
<tr>
<td>866.3120</td>
<td>Chlamydia serological reagents</td>
</tr>
<tr>
<td>866.3235</td>
<td>Epstein-Barr virus serological reagents</td>
</tr>
<tr>
<td>866.3370</td>
<td>Mycobacterium tuberculosis immunofluorescent reagents</td>
</tr>
<tr>
<td>866.3870</td>
<td>Trypanosoma spp. serological reagents</td>
</tr>
<tr>
<td>872.3700</td>
<td>Dental mercury</td>
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<tr>
<td>872.4200</td>
<td>Dental handpiece and accessories</td>
</tr>
<tr>
<td>872.6250</td>
<td>Dental chair and accessories(^4)</td>
</tr>
<tr>
<td>872.6640</td>
<td>Dental operative unit and accessories(^5)</td>
</tr>
<tr>
<td>872.6710</td>
<td>Boiling water sterilizer</td>
</tr>
<tr>
<td>878.5160</td>
<td>Urological clamps for males(^6)</td>
</tr>
<tr>
<td>878.4460</td>
<td>Surgeon’s glove</td>
</tr>
<tr>
<td>880.5090</td>
<td>Liquid bandage(^7)</td>
</tr>
<tr>
<td>880.5680</td>
<td>Pediatric position holder</td>
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<tr>
<td>880.6250</td>
<td>Patient examination glove</td>
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<tr>
<td>880.6375</td>
<td>Patient lubricant</td>
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<tr>
<td>880.6760</td>
<td>Protective restraint</td>
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<tr>
<td>882.1030</td>
<td>Ataxiograph</td>
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<tr>
<td>882.1420</td>
<td>Electroencephalogram (EEG) signal spectrum analyzer</td>
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<tr>
<td>882.4060</td>
<td>Ventricular cannula(^8)</td>
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<tr>
<td>882.4545</td>
<td>Shunt system implantation instrument(^9)</td>
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<tr>
<td>884.2980(a)</td>
<td>Telethermographic system(^{10})</td>
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<tr>
<td>884.2982(a)</td>
<td>Liquid crystal thermographic system(^{11})</td>
</tr>
<tr>
<td>884.5435</td>
<td>Unscented menstrual pads (interlabial pads and reusable menstrual pads)</td>
</tr>
<tr>
<td>885.4070</td>
<td>Powered corneal burr(^{12})</td>
</tr>
<tr>
<td>886.4300</td>
<td>Intraocular lens guide(^{13})</td>
</tr>
<tr>
<td>886.4370</td>
<td>Keratome</td>
</tr>
<tr>
<td>886.4750</td>
<td>Ophthalmic eye shield (when made of other than plastic or aluminum)</td>
</tr>
<tr>
<td>888.1500</td>
<td>Goniometer</td>
</tr>
<tr>
<td>890.3850</td>
<td>Mechanical wheelchair</td>
</tr>
<tr>
<td>890.5710</td>
<td>Hot or cold disposable pack(^{14})</td>
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<tr>
<td>892.1100</td>
<td>Scintillation (gamma) camera</td>
</tr>
<tr>
<td>892.1110</td>
<td>Positron camera</td>
</tr>
</tbody>
</table>

1 Meets reserved criteria for all assayed and only the unassayed when used for donor screening.
2 Meets reserved criteria when automated.
3 Meets reserved criteria when automated blood culturing systems.
4 Meets reserved criteria when dental chair with the operative unit.
5 Meets reserved criteria when it is not an accessory to the unit.
6 Meets reserved criteria when devices are for internal use or are used for females.
7 Meets reserved criteria for uses other than as a skin protectant.
8 Meets reserved criteria if not made of surgical grade stainless steel.
9 Meets reserved criteria if not made of surgical grade stainless steel.
10 Meets reserved criteria if an adjunct use system.
11 Meets reserved criteria if nonelectrically powered or AC-powered adjunctive system.
12 Meets reserved criteria if for use other than for removing rust rings.
13 Meets reserved criteria if used as folders or injectors for soft or foldable intraocular lenses (IOL’s).
14 Meets reserved criteria if indicated for use on infants.

FDA is amending the regulations to designate the following devices as exempt from premarket notification because FDA believes that they do not meet the reserved criteria under new section 510(l) of the act:

### TABLE 2—DESIGNATIONS OF EXEMPTED CLASS I DEVICES

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>Name of Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>862.1030</td>
<td>Alanine amino transferase (ALT/SGPT) test system</td>
</tr>
<tr>
<td>862.1040</td>
<td>Aldolase test system</td>
</tr>
<tr>
<td>862.1060</td>
<td>Delta-aminolevulinic acid test system</td>
</tr>
<tr>
<td>862.1075</td>
<td>Androstenedione test system</td>
</tr>
<tr>
<td>862.1080</td>
<td>Androsterone test system</td>
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<tr>
<td>862.1095</td>
<td>Ascorbic acid test system</td>
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<tr>
<td>862.1115</td>
<td>Urinary bilirubin and its conjugates (nonquantitative) test system</td>
</tr>
<tr>
<td>862.1130</td>
<td>Blood volume test system</td>
</tr>
<tr>
<td>862.1135</td>
<td>C-peptides of proinsulin test system</td>
</tr>
<tr>
<td>862.1165</td>
<td>Catecholamines (total) test system</td>
</tr>
<tr>
<td>862.1175</td>
<td>Cholesterol (total) test</td>
</tr>
<tr>
<td>862.1180</td>
<td>Chymotrypsin test system</td>
</tr>
<tr>
<td>862.1185</td>
<td>Compound S (11-deoxycortisol) test system</td>
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<tr>
<td>862.1195</td>
<td>Corticoids test system</td>
</tr>
<tr>
<td>21 CFR Section</td>
<td>Name of Device</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------</td>
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<tr>
<td>862.1200</td>
<td>Corticosterone test system</td>
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<tr>
<td>862.1240</td>
<td>Cystine test system</td>
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<tr>
<td>862.1245</td>
<td>Dehydroepiandrosterone (free and sulfate) test system</td>
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<tr>
<td>862.1250</td>
<td>Desoxycorticosterone test system</td>
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<tr>
<td>862.1260</td>
<td>Estradiol test system</td>
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<td>862.1265</td>
<td>Estriol test system</td>
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<tr>
<td>862.1270</td>
<td>Estrogens (total, in pregnancy) test system</td>
</tr>
<tr>
<td>862.1275</td>
<td>Estrogens (total, nonpregnancy) test system</td>
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<td>Estrone test system</td>
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<td>Gamma-glutamyl transpeptidase and isoenzymes test system</td>
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<td>Human growth hormone test system</td>
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<td>Histidine test system</td>
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<td>17-Hydroxycorticosteroids (17-ketogenic steroids) test system</td>
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<td>862.1390</td>
<td>5-Hydroxyindole acetic acid/serotonin test system</td>
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<td>862.1395</td>
<td>17-Hydroxyprogesterone test system</td>
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<td>Immunoreactive insulin test system</td>
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<td>17-Ketosteroids test system</td>
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<td>Ketones (nonquantitative) test system</td>
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<td>Lactic acid test system</td>
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<td>Malic dehydrogenase test system</td>
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<td>Mucopolysaccharides (nonquantitative) test system</td>
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<td>Nitrite (nonquantitative) test system</td>
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<td>5′-Nucleotidase test system</td>
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<td>Urinary pH (nonquantitative) test system</td>
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<td>Urinary phenylketones (nonquantitative) test system</td>
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<td>Porphyrins test system</td>
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<td>Pregnanediol test system</td>
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<td>Pregnanetriol test system</td>
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<td>Prolactin (lactogen) test system</td>
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<td>Urinary protein or albumin (nonquantitative) test system</td>
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<td>Quality control material (assayed and unassayed) 1</td>
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<td>Trypsin test system</td>
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<td>Urinary calculi (stones) test system</td>
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<td>Urinary urobilinogen (nonquantitative) test system</td>
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<td>Uroporphyrin test system</td>
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<td>Vitamin A test system</td>
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<td>Xylose test system</td>
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<td>Centrifugal chemistry analyzer for clinical use</td>
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<tr>
<td>862.2150</td>
<td>Continuous flow sequential multiple chemistry analyzer for clinical use</td>
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<tr>
<td>862.2160</td>
<td>Discrete photometric chemistry analyzer for clinical use</td>
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<td>862.2170</td>
<td>Micro chemistry analyzer for clinical use</td>
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<td>862.2250</td>
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<td>Thin-layer chromatography system for clinical use</td>
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<tr>
<td>862.2300</td>
<td>Colorimeter, photometer, or spectrophotometer for clinical use</td>
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<tr>
<td>862.2400</td>
<td>Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use</td>
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<td>862.2500</td>
<td>Enzyme analyzer for clinical use</td>
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<td>Flame emission photometer for clinical use</td>
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<td>21 CFR Section</td>
<td>Name of Device</td>
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<td>Fluorometer for clinical use</td>
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<td>Pipetting and diluting system for clinical use</td>
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<td>Clinical toxicology control material (assayed and unassayed)¹</td>
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<td>Cultured animal and human cells</td>
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<td>Specimen transport and storage container</td>
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<td>Vacuum-assisted blood collection system²</td>
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<td>Blood grouping view box</td>
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<td>864.9195</td>
<td>Blood mixing devices and blood weighing devices²</td>
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<td>864.9225</td>
<td>Cell-freezing apparatus and reagents for in vitro diagnostic use</td>
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<td>Blood bank centrifuge for in vitro diagnostic use</td>
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<td>Copper sulphate solution for specific gravity determinations</td>
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<td>Heat-sealing device</td>
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<td>Microorganism differentiation and identification device</td>
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<td>Aspergillus spp. serological reagents</td>
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<td>Corynebacterium spp. serological reagents</td>
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<td>Coxsackievirus serological reagents</td>
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<td>Echinococcus spp. serological reagents</td>
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<td>Equine encephalomyelitis virus serological reagents</td>
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<td>Lymphocytic choriomeningitis virus serological reagents</td>
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<td>Respiratory syncytial virus serological reagents</td>
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<td>Streptococcus spp. serological reagents</td>
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<td>Trichinella spiralis serological reagents</td>
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<td>Prealbumin immunological test system</td>
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<td>Beta-globulin immunological test system</td>
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<td>Carbonic anhydrase B and C immunological test</td>
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<td>Factor XIII, A, S, immunological test system³</td>
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<td>Alpha-globulin immunological test system</td>
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<td>Alpha-1-glycoproteins immunological test system</td>
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<td>Plasminogen immunological test system</td>
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<td>Prothrombin immunological test system⁴</td>
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<td>Retinol-binding protein immunological test system</td>
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<td>Inter-alpha trypsin inhibitor immunological test system</td>
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<td>868.1910</td>
<td>Esophageal stethoscope</td>
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<td>Breathing mouthpiece</td>
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<td>868.5640</td>
<td>Medicinal nonventilatory nebulizer (atomizer)</td>
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<td>Nebulizer device</td>
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<td>Nonpowered oxygen tent</td>
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<td>Tracheobronchial suction catheter</td>
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<td>872.3275(a)(1)</td>
<td>Dental cement (zinc oxide-eugenol)</td>
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<td>872.3400(b)(1)</td>
<td>Karaya and sodium borate with or without acacia denture adhesive (less than 12 percent sodium borate by weight)</td>
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<td>872.3540(b)(1)</td>
<td>OTC denture cushion or pad⁵</td>
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<td>Rubber dam and accessories⁶</td>
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<td>Short increment sensitivity index (SISI) adapter</td>
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<td>Earphone cushion for audiometric testing</td>
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<td>Toynbee diagnostic tube</td>
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<td>Hearing aid⁷</td>
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<tr>
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<td>Prosthesis modification instrument for ossicular replacement surgery</td>
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<td>Epistaxis balloon</td>
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<td>Ear, nose, and throat manual surgical instrument</td>
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<td>874.5300</td>
<td>Ear, nose, and throat examination and treatment unit</td>
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<td>Powered nasal irrigator</td>
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<tr>
<td>874.5840</td>
<td>Antistammering device</td>
</tr>
</tbody>
</table>
| 876.5160      | Urological clamp for males  

Exemption is limited to unassayed material, except when used in conjunction with donor screening tests.

2 Exemption is limited to manual devices.

3 This exemption should not be confused with 21 CFR 864.7290.

4 This exemption should not be confused with 21 CFR 864.5425 or 864.7750.

5 This exemption does not apply to class III OTC denture cushion as described in § 872.3540(b)(2).

6 Exemption does not include rubber dam intended for use in preventing transmission of sexually transmitted diseases through oral sex. Those devices are classified as condoms in 21 CFR 884.5300.

7 Exemption is limited to air-conduction hearing aids.

8 Exemption does not include devices for internal use or devices used for females.

9 Exemption does not include class II devices for a urine collector and accessories intended to be connected to an indwelling catheter as described in 21 CFR 876.5250(b)(1).

10 Exemption is limited to dissolvable nasogastric feed tube guide for the nasogastric tube in 21 CFR 876.5980(b)(2). Exemption does not include class II devices as described in § 876.5980(b)(1).

11 Exemption is limited to class I category other than surgical gowns and surgical masks.

12 Exemption is limited to use as a skin protectant.

13 Exemption is limited to devices made of surgical grade stainless steel.

14 Exemption is limited to devices made of surgical grade stainless steel.

15 Exemption should not be confused with 21 CFR 882.4305.

16 Exemption is limited to class I battery-powered devices.

17 Exemption is limited to rust ring removal.
preparation of such a premarket
biocompatibility. FDA estimates that
necessary for these devices would be
premarket notifications that are
with FDA. FDA anticipates that any
made of plastic or aluminum registered
ophthalmic eye shields other than those
A. Ophthalmic Eye Shield (When Made
These devices are as follows:
FDA is requiring premarket notification
requirements of premarket notification.
subject to the rule from the
Executive Order. In addition, the
philosophy and principles identified in
consistent with the regulatory
agency believes that this rule is
consistent with the regulatory
philosophy and principles identified in the
Executive Order. In addition, the
rule is not a significant regulatory action
as defined by the Executive Order and
so is not subject to review under the
Executive Order.
The Regulatory Flexibility Act
requires, if a rule has a significant impact on a substantial number of small entities, agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. In most cases, the rule would reduce a regulatory burden by exempting manufacturers of devices subject to the rule from the requirements of premarket notification. FDA is requiring premarket notification for three devices that were previously exempt from premarket notification. These devices are as follows:
A. Ophthalmic Eye Shield (When Made of Other Than Plastic or Aluminum) ($866.4750).
There are six manufacturers of
ophthalmic eye shields other than those made of plastic or aluminum registered with FDA. FDA anticipates that any premarket notifications that are necessary for these devices would be simple because FDA would be primarily interested in information about biocompatibility. FDA estimates that preparation of such a premarket notification would cost no more than $5,000 and that there would be no more than 6 premarket notifications per year for a total annual cost of $30,000.
Six manufacturers are not a substantial number of entities. Based on data compiled by the Small Business Administration, optical goods firms with fewer than 500 employees have annual receipts of $1,524,000. Therefore, the cost per firm of complying with this regulation ($5,000) does not have a significant impact on these small entities.
B. Quinine Test System ($862.3750) and Sul fonamide Test System ($862.3850).
At this time, there are no firms registered for manufacture of these devices.
In light of the previous discussion, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any one year.
VII. Paperwork Reduction Act of 1995
FDA concludes that this rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.
List of Subjects
21 CFR Parts 862, 866, 870, 872, 874, 876, 878, 880, 882, 884, 888, and 890
Medical devices.
21 CFR Part 864
Biologics, Blood, Laboratories, Medical devices, Packaging and containers.
21 CFR Part 866
Biologics, Laboratories, Medical devices.
21 CFR Part 886
Medical devices, Ophthalmic goods and services.
21 CFR Part 892
Medical devices, Radiation protection, X-rays.
Therefore, under the Federal Food, Drug, and Cosmetic Act and under
authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 890, 892, 894, 896, 888, 890, and 892 are amended as follows:
PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES
1. The authority citation for 21 CFR part 862 continues to read as follows:
2. Section 862.9 is revised to read as follows:
§ 862.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).
The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:
(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;
(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or
(c) The device is an in vitro device that is intended:
(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;
(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;
(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;
(4) For assessing the risk of cardiovascular diseases;
(5) For use in diabetes management;
(6) For identifying or inferring the identity of a microorganism directly from clinical material;
(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;
(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and
(9) For near patient testing (point of care).
3. Section 862.1030 is amended by revising paragraph (b) to read as follows:
§ 862.1030 Alanine amino transferase (ALT/SGPT) test system.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.
4. Section 862.1040 is amended by revising paragraph (b) to read as follows:
§ 862.1040 Aldolase test system.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.
5. Section 862.1060 is amended by revising paragraph (b) to read as follows:
§ 862.1060 Delta-aminolevulinic acid test system.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.
6. Section 862.1075 is amended by revising paragraph (b) to read as follows:
§ 862.1075 Androstenedione test system.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.
7. Section 862.1080 is amended by revising paragraph (b) to read as follows:
§ 862.1080 Androsterone test system.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.
8. Section 862.1095 is amended by revising paragraph (b) to read as follows:
§ 862.1095 Ascorbic acid test system.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.
9. Section 862.1115 is amended by revising paragraph (b) to read as follows:
§ 862.1115 Urinary bilirubin and its conjugates (nonquantitative) test system.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.
10. Section 862.1130 is amended by revising paragraph (b) to read as follows:
§ 862.1130 Blood volume test system.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.
11. Section 862.1135 is amended by revising paragraph (b) to read as follows:
§ 862.1135 C-peptides of proinsulin test system.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.
12. Section 862.1165 is amended by revising paragraph (b) to read as follows:
§ 862.1165 Catecholamines (total) test system.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

20. Section 862.1250 is amended by revising paragraph (b) to read as follows:

§ 862.1250 Desoxycorticosterone test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

21. Section 862.1260 is amended by revising paragraph (b) to read as follows:

§ 862.1260 Estradiol test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

22. Section 862.1265 is amended by revising paragraph (b) to read as follows:

§ 862.1265 Estriol test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

23. Section 862.1270 is amended by revising paragraph (b) to read as follows:

§ 862.1270 Estrogens (total, in pregnancy) test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

24. Section 862.1275 is amended by revising paragraph (b) to read as follows:

§ 862.1275 Estrogens (total, nonpregnancy) test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

25. Section 862.1280 is amended by revising paragraph (b) to read as follows:

§ 862.1280 Estrone test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

26. Section 862.1285 is amended by revising paragraph (b) to read as follows:

§ 862.1285 Estrone test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

27. Section 862.1300 is amended by revising paragraph (b) to read as follows:

§ 862.1300 Follicle-stimulating hormone test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

28. Section 862.1325 is amended by revising paragraph (b) to read as follows:

§ 862.1325 Gastrin test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

29. Section 862.1330 is amended by revising paragraph (b) to read as follows:

§ 862.1330 Globulin test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

30. Section 862.1335 is amended by revising paragraph (b) to read as follows:

§ 862.1335 Glucagon test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

31. Section 862.1360 is amended by revising paragraph (b) to read as follows:

§ 862.1360 Gamma-glutamyl transpeptidase and isoenzymes test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

32. Section 862.1370 is amended by revising paragraph (b) to read as follows:

§ 862.1370 Human growth hormone test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

33. Section 862.1375 is amended by revising paragraph (b) to read as follows:

§ 862.1375 Histidine test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

34. Section 862.1380 is amended by revising paragraph (b) to read as follows:

§ 862.1380 17-Hydroxycorticosteroids (17-ketogenic steroids) test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

35. Section 862.1390 is amended by revising paragraph (b) to read as follows:

§ 862.1390 5-Hydroxyindole acetic acid/serotonin test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

36. Section 862.1395 is amended by revising paragraph (b) to read as follows:

§ 862.1395 17-Hydroxyprogesterone test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

37. Section 862.1400 is amended by revising paragraph (b) to read as follows:

§ 862.1400 Hydroxyproline test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

38. Section 862.1405 is amended by revising paragraph (b) to read as follows:

§ 862.1405 Immunoreactive insulin test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the
premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

39. Section 862.1430 is amended by revising paragraph (b) to read as follows:

§ 862.1430 17-Ketosteroids test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

40. Section 862.1435 is amended by revising paragraph (b) to read as follows:

§ 862.1435 Ketones (nonquantitative) test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

41. Section 862.1440 is amended by revising paragraph (b) to read as follows:

§ 862.1440 Lactic acid test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

42. Section 862.1460 is amended by revising paragraph (b) to read as follows:

§ 862.1460 Leucine aminopeptidase test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

43. Section 862.1465 is amended by revising paragraph (b) to read as follows:

§ 862.1465 Lipase test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

44. Section 862.1475 is amended by revising paragraph (b) to read as follows:

§ 862.1475 Lipoprotein test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

45. Section 862.1485 is amended by revising paragraph (b) to read as follows:

§ 862.1485 Luteinizing hormone test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

46. Section 862.1500 is amended by revising paragraph (b) to read as follows:

§ 862.1500 Malic dehydrogenase test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

47. Section 862.1505 is amended by revising paragraph (b) to read as follows:

§ 862.1510 Nitrate (nonquantitative) test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

48. Section 862.1515 is amended by revising paragraph (b) to read as follows:

§ 862.1520 5′-Nucleotidase test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

49. Section 862.1530 is amended by revising paragraph (b) to read as follows:

§ 862.1530 Plasma oncometry test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

50. Section 862.1535 is amended by revising paragraph (b) to read as follows:

§ 862.1535 Ornithine carbamyl transferase test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

51. Section 862.1540 is amended by revising paragraph (b) to read as follows:

§ 862.1540 Osmolality test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

52. Section 862.1545 is amended by revising paragraph (b) to read as follows:

§ 862.1550 Urinary pH (nonquantitative) test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

53. Section 862.1560 is amended by revising paragraph (b) to read as follows:

§ 862.1560 Urinary phenylketones (nonquantitative) test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

54. Section 862.1570 is amended by revising paragraph (b) to read as follows:

§ 862.1570 Phosphohexose isomerase test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

55. Section 862.1580 is amended by revising paragraph (b) to read as follows:

§ 862.1580 Porphobilinogen test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.
§ 862.1605 Pregnenediol test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1606 Pregnanetriol test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1610 Pregnenolone test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1615 Pregnanetriol test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1620 Progesterone test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1625 Prolactin (lactogen) test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1630 Protein (fractionation) test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1635 Urinary protein or albumin (nonquantitative) test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1640 Urinary protein or albumin (quantitative) test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1645 Urinary protein or albumin (nonquantitative) test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1650 Pyruvate kinase test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1655 Pyruvic acid test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1660 Quality control material (assayed and unassayed).

(b) Classification. Class I (general controls). Except when used in donor screening tests, unassayed material is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1665 Uroporphyrin test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1670 Triglyceride test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1675 Trypsin test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1680 Urinary calculi (stones) test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1685 Urinary urobilinogen (nonquantitative) test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1690 Uroporphyrin test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1695 Vanilmandelic acid test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1700 Vitamin A test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1705 Vitamin A test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1710 Xylose test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1715 Xylose test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.
premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.
79. Section 862.2160 is amended by revising paragraph (b) to read as follows:

§ 862.2160 Discrete photometric chemistry analyzer for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

80. Section 862.2170 is amended by revising paragraph (b) to read as follows:

§ 862.2170 Micro chemistry analyzer for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

81. Section 862.2250 is amended by revising paragraph (b) to read as follows:

§ 862.2250 Gas liquid chromatography system for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

82. Section 862.2260 is amended by revising paragraph (b) to read as follows:

§ 862.2260 High pressure liquid chromatography system for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

83. Section 862.2270 is amended by revising paragraph (b) to read as follows:

§ 862.2270 Thin-layer chromatography system for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9. Particular components of TLC systems, i.e., the thin-layer chromatography apparatus, TLC atomizer, TLC developing tanks, and TLC ultraviolet light, are exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

84. Section 862.2300 is amended by revising paragraph (b) to read as follows:

§ 862.2300 Colorimeter, photometer, or spectrophotometer for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

85. Section 862.2400 is amended by revising paragraph (b) to read as follows:

§ 862.2400 Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

86. Section 862.2500 is amended by revising paragraph (b) to read as follows:

§ 862.2500 Enzyme analyzer for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

87. Section 862.2540 is amended by revising paragraph (b) to read as follows:

§ 862.2540 Flame emission photometer for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

88. Section 862.2560 is amended by revising paragraph (b) to read as follows:

§ 862.2560 Fluorometer for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

89. Section 862.2680 is amended by revising paragraph (b) to read as follows:

§ 862.2680 Microtiter for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

90. Section 862.2700 is amended by revising paragraph (b) to read as follows:

§ 862.2700 Nephelometer for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

91. Section 862.2730 is amended by revising paragraph (b) to read as follows:

§ 862.2730 Osmometer for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

92. Section 862.2750 is amended by revising paragraph (b) to read as follows:

§ 862.2750 Pipetting and diluting system for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

93. Section 862.2850 is amended by revising paragraph (b) to read as follows:

§ 862.2850 Atomic absorption spectrophotometer for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

94. Section 862.2860 is amended by revising paragraph (b) to read as follows:

§ 862.2860 Mass spectrometer for clinical use.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

95. Section 862.2900 is amended by revising paragraph (b) to read as follows:

§ 862.2900 Automated urinalysis system.
* * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

96. Section 862.3280 is amended by revising paragraph (b) to read as follows:

§ 862.3280 Clinical toxicology control material.
* * * *
(b) Classification. Class I (general controls). Except when used in donor screening, unassayed material is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

97. Section 862.3750 is amended by revising paragraph (b) to read as follows:
§ 864.3750 Quinine test system.
* * * * *
(b) Classification. Class I.

98. Section 862.3850 is amended by revising paragraph (b) to read as follows:

§ 862.3850 Sulfonylurea test system.
* * * * *
(b) Classification. Class I.

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

99. The authority citation for part 864 continues to read as follows:


100. Section 864.9 is revised to read as follows:

§ 864.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

101. Section 864.2280 is amended by revising paragraph (b) to read as follows:

§ 864.2280 Cultured animal and human cells.
* * * * *
(b) Classification. Class I (general controls).

102. Section 864.3250 is amended by revising paragraph (b) to read as follows:

§ 864.3250 Specimen transport and storage container.
* * * * *
(b) Classification. Class I (general controls).

103. Section 864.5240 is amended by revising paragraph (b) to read as follows:

§ 864.5240 Automated blood cell diluting apparatus.
* * * * *
(b) Classification. Class I (general controls).

104. Section 864.6150 is amended by revising paragraph (b) to read as follows:

§ 864.6150 Capillary blood collection tube.
* * * * *
(b) Classification. Class I (general controls).

105. Section 864.9125 is amended by revising paragraph (b) to read as follows:

§ 864.9125 Vacuum-assisted blood collection system.
* * * * *
(b) Classification. Class I (general controls).

106. Section 864.9185 is amended by revising paragraph (b) to read as follows:

§ 864.9185 Blood grouping view box.
* * * * *
(b) Classification. Class I (general controls).

107. Section 864.9195 is amended by revising paragraph (b) to read as follows:

§ 864.9195 Blood mixing devices and blood weighing devices.
* * * * *
(b) Classification. Class I (general controls).

108. Section 864.9225 is amended by revising paragraph (b) to read as follows:

§ 864.9225 Cell-freezing apparatus and reagents for in vitro diagnostic use.
* * * * *
(b) Classification. Class I (general controls).

109. Section 864.9275 is amended by revising paragraph (b) to read as follows:

§ 864.9275 Blood bank centrifuge for in vitro diagnostic use.
* * * * *
(b) Classification. Class I (general controls).

110. Section 864.9320 is amended by revising paragraph (b) to read as follows:
§ 866.9320 Copper sulfate solution for specific gravity determinations.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

111. Section 864.9750 is amended by revising paragraph (b) to read as follows:

§ 864.9750 Heat-sealing device.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

112. The authority citation for 21 CFR part 866 continues to read as follows:


113. Section 866.9 is revised to read as follows:

§ 866.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunohistochemistry; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material; and

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

114. Section 866.2660 is amended by revising paragraph (b) to read as follows:

§ 866.2660 Microorganism differentiation and identification device.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

115. Section 866.3040 is amended by revising paragraph (b) to read as follows:

§ 866.3040 Aspergillus spp. serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

116. Section 866.3140 is amended by revising paragraph (b) to read as follows:

§ 866.3140 Corynebacterium spp. serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

117. Section 866.3145 is amended by revising paragraph (b) to read as follows:

§ 866.3145 Cox sackievirus serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

118. Section 866.3200 is amended by revising paragraph (b) to read as follows:

§ 866.3200 Echinococcus spp. serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

119. Section 866.3240 is amended by revising paragraph (b) to read as follows:

§ 866.3240 Equine encephalomyelitis virus serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

120. Section 866.3355 is amended by revising paragraph (b) to read as follows:

§ 866.3355 Listeria spp. serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

121. Section 866.3360 is amended by revising paragraph (b) to read as follows:

§ 866.3360 Lymphocytic choriomeningitis virus serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

122. Section 866.3375 is amended by revising paragraph (b) to read as follows:

§ 866.3375 Mycoplasma spp. serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.
§ 866.3380 Mumps virus serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

124. Section 866.3480 is amended by revising paragraph (b) to read as follows:

§ 866.3480 Respiratory syncytial virus serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

128. Section 866.3500 is amended by revising paragraph (b) to read as follows:

§ 866.3500 Rickettsia serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

127. Section 866.3600 is amended by revising paragraph (b) to read as follows:

§ 866.3600 Schistosoma spp. serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

125. Section 866.3480 is amended by revising paragraph (b) to read as follows:

§ 866.3480 Respiratory syncytial virus serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

126. Section 866.3500 is amended by revising paragraph (b) to read as follows:

§ 866.3500 Rickettsia serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

127. Section 866.3600 is amended by revising paragraph (b) to read as follows:

§ 866.3600 Schistosoma spp. serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

128. Section 866.3680 is amended by revising paragraph (b) to read as follows:

§ 866.3680 Sporothrix schencki serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

129. Section 866.3740 is amended by revising paragraph (b) to read as follows:

§ 866.3740 Streptococcus spp. serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9. This exemption does not apply to factor deficiency tests classified under § 864.7290 of this chapter.

130. Section 866.3500 is amended by revising paragraph (b) to read as follows:

§ 866.3500 Rickettsia serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

131. Section 866.3680 is amended by revising paragraph (b) to read as follows:

§ 866.3680 Respiratory syncytial virus serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

132. Section 866.3500 is amended by revising paragraph (b) to read as follows:

§ 866.3500 Rickettsia serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

133. Section 866.3600 is amended by revising paragraph (b) to read as follows:

§ 866.3600 Schistosoma spp. serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

134. Section 866.3480 is amended by revising paragraph (b) to read as follows:

§ 866.3480 Respiratory syncytial virus serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

135. Section 866.3500 is amended by revising paragraph (b) to read as follows:

§ 866.3500 Rickettsia serological reagents.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

136. Section 866.5400 is amended by revising paragraph (b) to read as follows:

§ 866.5400 Alpha-globulin immunological test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

137. Section 866.5420 is amended by revising paragraph (b) to read as follows:

§ 866.5420 Alpha-1-glycoproteins immunological test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

138. Section 866.5425 is amended by revising paragraph (b) to read as follows:

§ 866.5425 Alpha-2-glycoproteins immunological test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

139. Section 866.5430 is amended by revising paragraph (b) to read as follows:

§ 866.5430 Beta-2-glycoprotein I immunological test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

140. Section 866.5440 is amended by revising paragraph (b) to read as follows:

§ 866.5440 Beta-2-glycoprotein II immunological test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

141. Section 866.5560 is amended by revising paragraph (b) to read as follows:

§ 866.5560 Lactic dehydrogenase immunological test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

142. Section 866.5570 is amended by revising paragraph (b) to read as follows:
§ 866.5710 Lactoferrin immunological test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

143. Section 866.5590 is amended by revising paragraph (b) to read as follows:

§ 866.5590 Lipoprotein X immunological test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

144. Section 866.5715 is amended by revising paragraph (b) to read as follows:

§ 866.5715 Plasminogen immunological test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

145. Section 866.5735 is amended by revising paragraph (b) to read as follows:

§ 866.5735 Prothrombin immunological test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

146. Section 866.5765 is amended by revising paragraph (b) to read as follows:

§ 866.5765 Retinol-binding protein immunological test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

147. Section 866.5890 is amended by revising paragraph (b) to read as follows:

§ 866.5890 Inter-alpha trypsin inhibitor immunological test system.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

PART 868—ANESTHESIOLOGY DEVICES

148. The authority citation for 21 CFR part 868 continues to read as follows:


149. Section 868.9 is revised to read as follows:

§ 868.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use whereas the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

150. Section 868.1910 is amended by revising paragraph (b) to read as follows:

§ 868.1910 Esophageal stethoscope.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

151. Section 868.5620 is amended by revising paragraph (b) to read as follows:

§ 868.5620 Breathing mouthpiece.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

152. Section 868.5640 is amended by revising paragraph (b) to read as follows:

§ 868.5640 Medicinal nonventilatory nebulizer (atomizer).

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

153. Section 868.5675 is amended by revising paragraph (b) to read as follows:

§ 868.5675 Rebreathing device.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

154. Section 868.5700 is amended by revising paragraph (b) to read as follows:

§ 868.5700 Nonpowered oxygen tent.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in
subpart E of part 807 of this chapter subject to § 868.9.

155. Section 868.6810 is amended by revising paragraph (b) to read as follows:

§ 868.6810 Tracheobronchial suction catheter.

* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

PART 870—CARDIOVASCULAR DEVICES

156. The authority citation for 21 CFR part 870 continues to read as follows:


157. Section 870.9 is revised to read as follows:

§ 870.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

PART 872—DENTAL DEVICES

158. The authority citation for 21 CFR part 872 continues to read as follows:


159. Section 872.9 is revised to read as follows:

§ 872.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

160. Section 872.3275 is amended by revising paragraph (a)(2) to read as follows:

§ 872.3275 Dental cement.

(a) * * *

(2) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 872.9.

* * * * *
161. Section 872.3400 is amended by revising paragraph (b)(1) to read as follows:

§ 872.3400  Karaya and sodium borate with or without acacia denture adhesive.

* * * * *

(b) Classification. (1) Class I (general controls) if the device contains less than 12 percent by weight of sodium borate. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 872.9.

162. Section 872.3540 is amended by revising paragraph (b)(1) to read as follows:

§ 872.3540  OTC denture cushion or pad.

* * * * *

(b) Classification. (1) Class I if the device is made of wax-impregnated cotton cloth that the patient applies to the base or inner surface of a denture before inserting the denture into the mouth. The device is intended to be discarded following 1 day’s use. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 872.9.

163. Section 872.6300 is revised to read as follows:

§ 872.6300  Rubber dam and accessories.

(a) Identification. A rubber dam and accessories is a device composed of a thin sheet of latex with a hole in the center intended to isolate a tooth from fluids in the mouth during dental procedures, such as filling a cavity preparation. The device is stretched around a tooth by inserting a tooth through a hole in the center. The device includes the rubber dam, rubber dam clamp, rubber dam frame, and forceps for a rubber dam clamp. This classification does not include devices intended for use in preventing transmission of sexually transmitted diseases through oral sex; those devices are classified as condoms in § 884.5300 of this chapter.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

164. Section 872.6390 is amended by revising paragraph (b) to read as follows:

§ 872.6390  Dental floss.

* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 872.9.

165. Section 872.6640 is amended by revising paragraph (b) to read as follows:

§ 872.6640  Dental operative unit and accessories.

* * * * *

(b) Classification. Class I (general controls). Except for dental operative unit, accessories are exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to § 872.9.

PART 874—EAR, NOSE, AND THROAT DEVICES

166. The authority citation for 21 CFR part 874 continues to read as follows:


167. Section 874.9 is revised to read as follows:

§ 874.9  Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for a different use where the former intended use was by health care professionals only; or

(b) The modified device operates using a fundamental scientific technology rather than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

168. Section 874.1070 is amended by revising paragraph (b) to read as follows:

§ 874.1070  Short increment sensitivity index (SISI) adapter.

* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9.

169. Section 874.1100 is amended by revising paragraph (b) to read as follows:

§ 874.1100  Earphone cushion for audiometric testing.

* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9.

170. Section 874.1500 is amended by revising paragraph (b) to read as follows:

§ 874.1500  Gustometer.

* * * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with respect to general requirements concerning records, and §820.198 of this chapter, with respect to complaint files.

172. Section 874.1925 is amended by revising paragraph (b) to read as follows:

§874.1925  Toynbee diagnostic tube.  

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.

173. Section 874.3300 is amended by revising paragraph (b) to read as follows:

§874.3300  Hearing aid.  

(b) Classification. (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.

(2) Class II for the bone-conduction hearing aid.

174. Section 874.3540 is amended by revising paragraph (b) to read as follows:

§874.3540  Prosthesis modification instrument for ossicular replacement surgery.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning records, and §820.198 of this chapter, with respect to complaint files.

175. Section 874.4100 is amended by revising paragraph (b) to read as follows:

§874.4100  Epistaxis balloon.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.

176. Section 874.4420 is amended by revising paragraph (b) to read as follows:

§874.4420  Ear, nose, and throat manual surgical instrument.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.

177. Section 874.5300 is amended by revising paragraph (b) to read as follows:

§874.5300  Ear, nose, and throat examination and treatment unit.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.

178. Section 874.5550 is amended by revising paragraph (b) to read as follows:

§874.5550  Powered nasal irrigator.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.

179. Section 874.5840 is amended by revising paragraph (b) to read as follows:

§874.5840  Antistammering device.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.

PART 876—GASTROENTEROLOGY–UROLOGY DEVICES

180. The authority citation for 21 CFR part 876 continues to read as follows:


181. Section 876.9 is revised to read as follows:

§876.9  Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in §812.3(k) of this chapter; and
§ 876.5160 Urological clamp for males.

(b) Classification. Class I (general controls). Except when intended for internal use or use on females, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

183. Section 876.5210 is amended by revising paragraph (b) to read as follows:

§ 876.5210 Enema kit.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

184. Section 876.5250 is amended by revising paragraph (b)(2) to read as follows:

§ 876.5250 Urine collector and accessories.

(b) * * *

(2) Class I (general controls) for a urine collector and accessories not intended to be connected to an indwelling catheter. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to the general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

185. Section 876.5980 is amended by revising paragraph (b)(2) to read as follows:

§ 876.5980 Gastrointestinal tube and accessories.

(b) * * *

(2) Class I (general controls) for the dissolvable nasogastric feed tube guide for the nasogastric tube. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

186. The authority citation for 21 CFR part 878 continues to read as follows:


187. Section 878.9 is revised to read as follows:

§ 878.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for use in a lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

188. Section 878.3250 is amended by revising paragraph (b) to read as follows:

§ 878.3250 External facial fracture fixation appliance.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

189. Section 878.3910 is amended by revising paragraph (b) to read as follows:

§ 878.3910 Noninflatable extremity splint.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

190. Section 878.3925 is amended by revising paragraph (b) to read as follows:

§ 878.3925 Plastic surgery kit and accessories.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.
§ 878.4040 Surgical apparel.
   * * * * *
   (b) Classification. (1) Class II (special controls) for surgical gowns and surgical masks.
   (2) Class I (general controls) for surgical apparel other than surgical gowns and surgical masks. The Class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

192. Section 878.4100 is amended by revising paragraph (b) to read as follows:

§ 878.4100 Organ bag.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

193. Section 878.4200 is amended by revising paragraph (b) to read as follows:

§ 878.4200 Introduction/drainage catheter and accessories.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

194. Section 878.4320 is amended by revising paragraph (b) to read as follows:

§ 878.4320 Removable skin clip.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

195. Section 878.4680 is amended by revising paragraph (b) to read as follows:

§ 878.4680 Nonpowered, single patient, portable suction apparatus.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

196. Section 878.4760 is amended by revising paragraph (b) to read as follows:

§ 878.4760 Removable skin staple.
   * * * * *
   (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

197. Section 878.4820 is amended by revising paragraph (b) to read as follows:

§ 878.4820 Surgical instrument motors and accessories/attachments.
   * * * * *
203. Section 880.5420 is amended by revising paragraph (b) to read as follows:

§880.5420 Pressure infusor for an I.V. bag.
* * * * *
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §880.9.

PART 882—NEUROLOGICAL DEVICES

204. The authority citation for 21 CFR part 882 continues to read as follows:


205. Section 882.9 is revised to read as follows:

§882.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; (b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in §812.3(k) of this chapter; and

(9) For near patient testing (point of care).

206. Section 882.1200 is amended by revising paragraph (b) to read as follows:

§882.1200 Two-point discriminator.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §882.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning records, and §820.198 of this chapter, with respect to complaint files.

207. Section 882.1500 is amended by revising paragraph (b) to read as follows:

§882.1500 Esthesiometer.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §882.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning records, and §820.198 of this chapter, with respect to complaint files.

208. Section 882.1750 is amended by revising paragraph (b) to read as follows:

§882.1750 Pinwheel.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §882.9.

209. Section 882.4060 is amended by revising paragraph (b) to read as follows:

§882.4060 Ventricular cannula.
* * * * *

(b) Classification. Class I (general controls). When made only of surgical grade stainless steel, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §882.9.

210. Section 882.4545 is amended by revising paragraph (b) to read as follows:

§882.4545 Shunt system implantation instrument.
* * * * *

(b) Classification. Class I (general controls). When made only of surgical grade stainless steel, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §882.9.

211. Section 882.4650 is amended by revising paragraph (b) to read as follows:

§882.4650 Neurosurgical suture needle.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §882.9.

212. Section 882.4750 is amended by revising paragraph (b) to read as follows:

§882.4750 Skull punch.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §882.9. This exemption does not apply to powered compound cranial drills, burrs, trephines, and their accessories classified under §882.4305.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

213. The authority citation for 21 CFR part 884 continues to read as follows:


214. Section 884.9 is revised to read as follows:

§884.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I
or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

215. Section 884.1040 is amended by revising paragraph (b) to read as follows:

§ 884.1040 Viscometer for cervical mucus.

(a) Classification. Class I (general controls).

(b) The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 884.9.

§ 884.5435 [Amended]

216. Section 884.5435 Unscented menstrual pad is amended in the last sentence of paragraph (b) by removing the word “intralabial” and adding in its place the word “interlabial”.

PART 886—OPHTHALMIC DEVICES

217. The authority citation for use part 886 continues to read as follows:


218. Section 886.9 is revised to read as follows:

§ 886.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(b) Classification. (1) Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 884.9.

§ 886.1350 Keratoscope.

(a) The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9. The battery-powered device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.196 of this chapter, with respect to complaint files.

220. Section 886.1780 is amended by revising paragraph (b) to read as follows:

§ 886.1780 Retinoscope.

(a) Classification. (1) Class II (special controls) for the AC-powered device. (2) Class I (general controls) for the battery-powered device. The class I
battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9. The battery-powered device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

221. Section 866.1940 is amended by revising paragraph (b) to read as follows:

§ 886.1940 Tonometer sterilizer.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

222. Section 886.4070 is amended by revising paragraph (b) to read as follows:

§ 886.4070 Powered corneal burr.

(b) Classification. Class I (general controls). When intended only for rust ring removal, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

223. Section 886.4300 is amended by revising paragraph (b) to read as follows:

§ 886.4300 Intraocular lens guide.

(b) Classification. Class I (general controls). Except when used as folders or injectors for soft or foldable intraocular lenses, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

224. Section 886.4750 is amended by revising paragraph (b) to read as follows:

§ 886.4750 Ophthalmic eye shield.

(b) Classification. Class I (general controls). When made only of plastic or aluminum, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9. When made only of plastic or aluminum, the device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

225. Section 886.5850 is amended by revising paragraph (b) to read as follows:

§ 886.5850 Sunglasses (nonprescription).

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

PART 888—ORTHOPEDIC DEVICES

226. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360(e), 360(j), 371.

227. Section 888.9 is revised to read as follows:

§ 888.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

PART 890—PHYSICAL MEDICINE DEVICES

228. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360(e), 360(j), 371.

229. Section 890.9 is revised to read as follows:

§ 890.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;
purpose, or the device is intended for lay use where the former intended use was by health care professionals only; (b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or (c) The device is an in vitro device that is intended: (1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices; (2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism; (3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy; (4) For assessing the risk of cardiovascular diseases; (5) For use in diabetes management; (6) For identifying or inferring the identity of a microorganism directly from clinical material; (7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma; (8) For noninvasive testing as defined in §812.3(k) of this chapter; and (9) For near patient testing (point of care).

230. Section 890.5180 is amended by revising paragraph (b) to read as follows:

§890.5180 Manual patient rotation bed. * * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §890.9.

PART 892—RADIOLOGY DEVICES

232. The authority citation for 21 CFR part 892 continues to read as follows: Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

233. Section 892.9 is revised to read as follows:

§892.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of an in vitro diagnostic device, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when: (a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; (b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or (c) The device is an in vitro device that is intended: (1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices; (2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism; (3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy; (4) For assessing the risk of cardiovascular diseases; (5) For use in diabetes management; (6) For identifying or inferring the identity of a microorganism directly from clinical material; (7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma; (8) For noninvasive testing as defined in §812.3(k) of this chapter; and (9) For near patient testing (point of care).

234. Section 892.1300 is amended by revising paragraph (b) to read as follows:

§892.1300 Nuclear rectilinear scanner. * * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §892.9.

235. Section 892.1320 is amended by revising paragraph (b) to read as follows:

§892.1320 Nuclear uptake probe. * * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §892.9.

236. Section 892.1330 is amended by revising paragraph (b) to read as follows:

§892.1330 Nuclear whole body scanner. * * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §892.9.

237. Section 892.1350 is amended by revising paragraph (b) to read as follows:

§892.1350 Nuclear scanning bed. * * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §892.9.
premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.

239. Section 892.1890 is amended by revising paragraph (b) to read as follows:

§ 892.1890 Radiographic film illuminator.

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(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.

240. Section 892.1910 is amended by revising paragraph (b) to read as follows:

§ 892.1910 Radiographic grid.

* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.

241. Section 892.1960 is amended by revising paragraph (b) to read as follows:

§ 892.1960 Radiographic intensifying screen.

* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.

242. Section 892.1970 is amended by revising paragraph (b) to read as follows:


* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.

243. Section 892.2010 is amended by revising paragraph (b) to read as follows:

§ 892.2010 Medical image storage device.

* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.

244. Section 892.2020 is amended by revising paragraph (b) to read as follows:

§ 892.2020 Medical image communications device.

* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.

245. Section 892.5650 is amended by revising paragraph (b) to read as follows:

§ 892.5650 Manual radionuclide applicator system.

* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.

246. Section 892.6500 is amended by revising paragraph (b) to read as follows:

§ 892.6500 Personnel protective shield.

* * * * *

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.


Linda S. Kahan,
Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 8659]

RIN 1545–AV44

Compliance Monitoring and Miscellaneous Issues Relating to the Low-Income Housing Credit

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations regarding the procedures for compliance monitoring by state and local housing agencies (Agencies) with the requirements of the low-income housing credit; the requirements for making carryover allocations; the rules for Agencies’ correction of administrative errors or omissions; and the independent verification of information on sources and uses of funds submitted by taxpayers to Agencies. These final regulations affect owners of low-income housing projects who claim the credit and the Agencies who administer the credit.

DATES: Effective Dates: These regulations are effective January 1, 2001, except that the amendments made to §§ 1.42–5(c)(5) and (e)(3)(i), and 1.42–13 are effective January 14, 2000, and the amendment made to § 1.42–6(d)(4)(ii) is effective January 1, 2000.

Applicability Dates: For dates of applicability of the amendments to § 1.42–5, see § 1.42–5(h). For date of applicability of the amendment made to § 1.42–6, see § 1.42–12(c). For date of applicability of the amendments made to § 1.42–13, see § 1.42–13(d). For date of applicability of § 1.42–17, see § 1.42–17(b).

FOR FURTHER INFORMATION CONTACT: Paul Handleman, (202) 622–3040 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in these final regulations have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) under control numbers 1545–1357. Responses to these collections of information are mandatory. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

For § 1.42–5, the estimated annual burden per respondent varies from .5 hour to 3 hours for taxpayers and 250 to 5,000 hours for Agencies, with an estimated average of 1 hour for taxpayers and 1,500 hours for Agencies. For § 1.42–13, the estimated annual burden per respondent varies from .5 hour to 10 hours for taxpayers and Agencies, with an estimated average of 3.5 hours for taxpayers and 3 hours for Agencies. For § 1.42–17, the estimated annual burden per respondent varies from .5 hour to 2 hours for taxpayers and .5 hour to 5 hours for Agencies, with an estimated average of 1 hour for taxpayers and 2 hours for Agencies.

Comments concerning the accuracy of these burden estimates and suggestions for reducing these burdens should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, OP:FS:FP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to this collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

On January 8, 1999, the IRS published proposed regulations (REG–114664–97) in the Federal Register (64 FR 1143) inviting comments under section 42. A