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Dated: October 28, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 864, 866, 876, 880, 882, 886, 890, and 892

[Docket No. 98-0015]

Medical Devices; Exemptions From Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is codifying the exemption from premarket notification of all 62 class II (special controls) devices listed as exempt in a January 21, 1998, **Federal Register** notice, subject to the limitations on exemptions. FDA has determined that for these exempted devices, manufacturers' submissions of premarket notifications are unnecessary to provide a reasonable assurance of safety and effectiveness. These devices will remain subject to current good manufacturing practice (CGMP) regulations and other general controls. This rulemaking implements new authorities delegated to FDA under the Food and Drug Administration Modernization Act (FDAMA).

EFFECTIVE DATE: November 3, 1998.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 21, 1998 (63 FR 3142) (hereinafter referred to as the January 21, 1998, notice), FDA issued a notice stating that 62 class II (special controls) devices were exempt from the requirement of premarket notification, with limitations. This notice was issued in accordance with

FDAMA (Pub. L. 105-115), which the President signed into law on November 21, 1997. Section 206 of FDAMA, in part, added a new section 510(m) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(m)). Section 510(m)(1) of the act required FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act (generally referred to as a premarket notification or "510(k)") to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provided that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. Interested persons were given until April 20, 1998, to comment on the notice.

Section 510(m)(2) of the act also provides that, 1 day after date of publication of the list under section 510(m)(1) FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device.

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. Indeed, FDA's determination that premarket notification was unnecessary to provide a reasonable assurance of safety and effectiveness for devices listed in this document was based, in part, on the assurance of safety and effectiveness that other regulatory controls, such as current good manufacturing practice requirements, provide. Persons with pending 510(k) submissions for devices that are now exempt from premarket notification, subject to the limitations on exemptions, should withdraw their submissions.

FDA is codifying the exemption from premarket notification of all 62 class II devices listed as exempt in the January 21, 1998, notice, subject to the limitations on exemptions. These devices will remain subject to CGMP requirements and other general controls under the statute as well as any special controls.

The Administrative Procedure Act (the APA) (Pub. L. 79-404) and FDA regulations provide that the agency may issue a regulation without notice and comment procedures when the agency for good cause finds (and incorporates the finding and a brief statement of reasons thereof in the rules issued) that notice and public procedure thereon are

impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(8), § 10.40(e)(1) (21 CFR 10.40).) The Commissioner of Food and Drugs (the Commissioner) finds for good cause that there is reason to dispense with notice and comment rulemaking to amend the codified language in the Code of Federal Regulations (CFR) to reflect that certain class II devices are exempt.

Notice and comment rulemaking to codify the exemptions for these class II devices would be both impracticable and unnecessary. As previously stated, under the authority provided by section 206 of FDAMA, these exemptions have already taken effect by operation of the statute on January 21, 1998. Accordingly, it is both impracticable and unnecessary to provide notice and comment on a regulation that merely codifies that which has already occurred. Furthermore, interested persons were provided an opportunity to comment when the January 21, 1998, notice published.

II. Effective Date

Section 553(d) of the APA requires that the effective date of a substantive rule shall occur not less than 30 days after the publication or service unless, under section 553(d)(1), the rule grants or recognizes an exemption or relieves a restriction, or unless, under section 553(d)(3), the agency finds good cause to make the effective date less than 30 days and publishes the basis with the rule.

The Commissioner finds that because the exemptions are already in effect, providing a delayed effective date for the regulation conforming the CFR to reflect the exemptions is impracticable and unnecessary. Accordingly, there is good cause, under section 553(d)(3) of the APA and § 10.40(c)(4)(ii), to provide an immediate effective date. Additionally, an immediate effective date is authorized under section 553(d)(1) and § 10.40(c)(4)(i) because the codification of the exemptions recognizes an exemption.

III. Comments

FDA received 8 sets of comments from respondents, both supporting and opposing the exemption of the 62 class II devices.

1. Two comments suggested that FDA remove the following in vitro diagnostic, class II devices from the list of exempted devices: 21 CFR 866.3060 *Blastomyces dermatitidis*, 866.3085 *Brucella spp. serological reagents*, 866.3135 *Coccidioides immitis serological reagents*, 866.3320 *Histoplasma capsulatum serological reagents*, 866.3165 *Cryptococcus*

neoformans serological reagents, 866.3220 *Entamoeba histolytica serological reagents*, 866.3280 *Francisella tularensis serological reagents*, 866.3350 *Leptospira spp. serological reagents*, and 866.3460 *Rabiesvirus immunofluorescent reagents*. The comments stated that these devices fail to meet the criteria for exemption as described in the regulatory notice as "Limitations on Exemptions." Also, a third comment suggested that two "in vitro devices * * * intended for the screening of familial and acquired genetic disorders" (21 CFR 866.5210 *Ceruloplasmin immunological test system* and 866.5470 *Hemoglobin immunological test system*) fail to meet criteria for exemption under FDAMA.

Devices that are listed as exempt from 510(k) requirements are subject to the limitations to those exemptions described in the January 21, 1998, notice. The limitations to the exemptions state that for certain uses, in vitro diagnostic devices that are otherwise exempt are still subject to 510(k) requirements. Accordingly, a generic device type may be exempt from 510(k) requirements for some uses, and not exempt from those requirements if it is intended for other uses described in the limitations language. For example, the January 21, 1998, notice states that a generic type of device that is otherwise exempt is not exempt if it is used in screening or diagnosis of familial and acquired genetic disorders, or for measuring analytes that serve as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases.

FDA does not agree that all the marketed uses for the devices addressed by the comments (with the exceptions of rabiesvirus immunofluorescent reagents, the ceruloplasmin immunological test system, and the hemoglobin immunological test system) fall within the limitations to the exemptions language in the January 21, 1998, notice. These devices can be exempt, for example, when they are marketed for the determination of immune status, or for epidemiological uses. If these same devices, however, are used in the diagnosis of a life-threatening disease, they would not be exempt.

FDA agrees, however, that all marketed uses for rabiesvirus immunofluorescent reagents are for the detection of rabies, a life-threatening disease, and that all marketed uses for the ceruloplasmin immunological test system and the hemoglobin immunological test system are for the screening or diagnosis of familial and acquired genetic disorders. Accordingly, all intended uses for these devices

would fall within the limitations to exemptions for devices that are for use in screening or diagnosis of familial and acquired genetic disorders, or for measuring analytes that serve as surrogate markers for screening, diagnosis, or monitoring life-threatening diseases.

FDA believes that it erroneously listed the generic device types rabiesvirus immunofluorescent reagents, ceruloplasmin immunological test systems, and hemoglobin immunological test systems as exempt from 510(k) requirements in the January 21, 1998, notice. Therefore, FDA intends to issue a proposal to clarify that none of these devices are exempt from 510(k) requirements. Until such rulemaking is final, however, these devices will be listed, in accordance with the January 21, 1998, notice, as exempt subject to the limitations to the exemptions. Sponsors should be aware, however, that FDA believes that all marketed uses for these devices fall within the limitations to the exemptions, and that sponsors, therefore, should continue to submit 510(k) submissions.

2. One comment requested more information on devices covered by 21 CFR 864.9160 *Blood group substances of nonhuman origin for in vitro diagnostic use*.

FDA believes that devices in this classification traditionally have been used for neutralization studies to assist in identification of antibodies in patients with multiple antibodies. There does not appear to be a high demand for these devices. FDA believes that there are quality control practices and procedures in place that make continued active premarket regulation unnecessary to ensure safety and effectiveness.

3. The Health Care Financing Administration (HCFA) raised concerns about the effect that exemptions may have on HCFA's implementation of the Clinical Laboratory Improvements Amendments. HCFA subsequently commented that they believed that their concerns could be addressed without affecting the exemption process.

FDA intends to continue to meet with the HCFA staff to address these concerns, which relate to inspection procedures in laboratories.

4. One comment questioned the limitations on exemptions stated in the January 21, 1998, notice, particularly the limitations applicable to in vitro diagnostic devices that are noninvasive tests. The comment criticized the use of the words "noninvasive testing" as being overly broad.

FDA disagrees with this comment. FDA believes that the limitations are necessary to ensure that devices are not

marketed that are significantly different from the devices exempted from premarket notification, particularly in the area of in vitro diagnostic devices where devices are often subject to changes in intended use and conditions of use. Noninvasive testing devices should not be exempt because they almost always involve novel matrices and novel technologies.

5. One comment suggested that the limitations on exemptions are unnecessary, confusing, and difficult to apply, especially to in vitro diagnostic devices. This comment additionally notes "we question the basis for FDA's broad restrictions in such a specific category of devices."

FDA does not agree that the language is unnecessary, confusing, or difficult to apply. The limitations language in the January 21, 1998, notice, that applies to class II devices listed therein, modifies the limitations on exemptions currently found in ".9" of each device classification regulation part (e.g., 21 CFR 862.9, 864.9, etc.) only in three ways. First, FDA has referenced class II devices to reflect that class II devices may be exempted in accordance with new section 510(m) of the act. Second, the limitations language modifies current limitations language by stating that devices are to be compared to "any legally marketed device in that generic type of device" rather than a device on the market "before May 28, 1976" or a "preamendments device to which it has been determined substantially equivalent." Third, the limitations language adds specific language relating to in vitro diagnostic devices. The agency cannot predict all possible different intended uses or changes in fundamental scientific technologies that may significantly affect safety and effectiveness; limitations on exemptions are, therefore, in the best interest of the public health because they ensure that devices incorporating such changes will be reviewed for safety and effectiveness by the agency before they go to market. Furthermore, FDA believes that in vitro diagnostic devices are unique because their safety and effectiveness relates primarily to the information generated by these devices rather than the direct interaction between device and patient. FDA has more fully discussed the need for these limitations in the January 21, 1998, notice. In order to efficiently allocate review resources, the agency has developed a risk-based approach toward use of the limitations on exemptions to ensure that high-risk devices remain subject to premarket review. The limitations on exemptions continue to take into account two

critical risk elements: Intended use and novelty of technology.

6. One comment stated that body fat testers meet the criteria for exemption from 510(k) and should therefore be exempt. Another comment stated that film dosimetry systems are quality control devices and should not be regulated as a class II device.

Neither of these devices were listed as exempt in the January 21, 1998, notice. Body fat analyzers have been found to be substantially equivalent to legally marketed devices classified under 21 CFR 870.2770 *Impedance plethysmograph*. Film dosimetry systems are regulated under 21 CFR 892.5050 *Medical charged-particle radiation therapy system*. This document is codifying the exemptions only for devices listed in the January 21, 1998, notice.

Under new section 510(m)(2) of the act, any person now may petition the agency for additional exemptions from the requirements of 510(k) for a class II device type. FDA has provided guidance for submitting a petition for exemption of a class II device and has requested that these comments submit such petitions for these device types.

7. One comment believed the limitations on exemptions required clarification as follows:

With regard to the first limitation ("has an intended use that is different from the intended use of a legally marketed device in that generic type"), we believe that current law is clear that if a device has an intended use different than that expressed in the definition contained in the Code of Federal Regulations (CFR), such device would not be the same as the exempted device. The exemption would simply not apply to that device. However, "intended use" can encompass many different concepts that go beyond the general intended use statements that comprised the CFR definitions. There has been some controversy, for instance, over the extent to which indications for use can change intended use. Our position is that any indication for use that has been included in a previous 510(k) order of classification identifies the scope of the intended use for each exempt type of device. Minor variances of indications for use within the intended use of an exempt type of device should have no effect on the status of a 510(k) exemption.

FDA has interpreted paragraph ".9(a)" of each device classification regulation part (e.g., 21 CFR 862.9, 864.9, etc.) in the limitations on exemptions under the current regulation to mean that any legally marketed device (as defined in 21 CFR 807.92(a)(3)) within a device classification regulation, may serve as a predicate for another manufacturer's device, and the other manufacturer's device may be exempt. FDA believes that any additional indication for use for an exempt classification device type

(i.e., an indication not previously cleared) is considered a different intended use and does not meet the limitations on exemptions, and therefore, requires a new premarket notification. FDA agrees that minor variances in indications would not affect the exemption status of the classification. FDA notes that in our guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device," FDA states, in regard to minor variances in indications of closely related populations, "If the expansion is to a population with similar demographics, diagnosis, prognosis, comorbidity and potential for complications as the original, then a new 510(k) is not ordinarily expected."

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment or an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612), and under the Unfunded Mandates Reform Act (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy on principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

If there is a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule would reduce a regulatory burden by exempting manufacturers of devices subject to the requirements of premarket notification, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore,

under the Regulatory Flexibility Act, no further analysis is required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance from the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects

21 CFR Parts 862, 876, 880, 882, and 890

Medical devices.

21 CFR Part 864

Blood, 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 Drug, 21 CFR parts 862, 864, 866, 876, 880, 882, 886, 890, and 892 are amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation 21 CFR part 862 continues to read as follows:

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

2. Section 862.9 is amended by revising the section heading, by designating the introductory text as paragraph (a), by redesignating paragraphs (a) and (b) as paragraphs (a)(1) and (a)(2), respectively, and by adding new paragraph (b) to read as follows:

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

* * * * *

(b) The exemption from the requirement of premarket notification for a generic type of class II device applies only to those class II devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with

high morbidity or mortality. A class II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification when:

(1) 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

(2) 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

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

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

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

(iii) 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;

(iv) For use in assessing the risk of cardiovascular diseases;

(v) For use in diabetes management;

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

(vii) 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;

(viii) For noninvasive testing; and

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

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

§ 862.1440 Lactate dehydrogenase test system.

* * * * *

(b) *Classification.* Class II (special 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 862.1635 is amended by revising paragraph (b) to read as follows:

§ 862.1635 Total protein test system.

* * * * *

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

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

5. The authority citation for 21 CFR part 864 continues to read as follows:

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

6. Section 864.9 is amended by designating the introductory text as paragraph (a), by redesignating paragraphs (a) and (b) as paragraphs (a)(1) and (a)(2), respectively, and by adding new paragraph (b) to read as follows:

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

* * * * *

(b) The exemption from the requirement of premarket notification for a generic type of class II device applies only to those class II devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. A class II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification when:

(1) 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

(2) 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

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

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

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

(iii) 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;

(iv) For assessing the risk of cardiovascular diseases;

(v) For use in diabetes management;

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

(vii) 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;

(viii) For noninvasive testing; and

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

7. Section 864.6100 is amended by revising paragraph (b) to read as follows:

§ 864.6100 Bleeding time device.

* * * * *

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

8. Section 864.6400 is amended by revising paragraph (b) to read as follows:

§ 864.6400 Hematocrit measuring device.

* * * * *

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

9. Section 864.9160 is amended by revising paragraph (b) to read as follows:

§ 864.9160 Blood group substance of nonhuman origin for in vitro diagnostic use.

* * * * *

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

10. Section 864.9550 is amended by revising paragraph (b) to read as follows:

§ 864.9550 Lectins and protectins.

* * * * *

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

11. Section 864.9575 is amended by revising paragraph (b) to read as follows:

§ 864.9575 Environmental chamber for storage of platelet concentrate.

* * * * *

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

12. Section 864.9600 is amended by revising paragraph (b) to read as follows:

§ 864.9600 Potentiating media for in vitro diagnostic use.

* * * * *

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

13. Section 864.9700 is amended by revising paragraph (b) to read as follows:

§ 864.9700 Blood storage refrigerator and blood storage freezer.

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(b) *Classification.* Class II (special 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

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

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

15. Section 866.9 is amended by designating the introductory text as paragraph (a), by redesignating paragraphs (a) and (b) as paragraphs (a)(1) and (a)(2), respectively, and by adding new paragraph (b) to read as follows:

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

* * * * *

(b) The exemption from the requirement of premarket notification for a generic type of class II device applies only to those class II devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. A class II

device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification when:

(1) 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

(2) 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

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

- (i) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;
- (ii) For use in screening or diagnosis of familial and acquired genetic disorders, including inborn errors of metabolism;
- (iii) 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;
- (iv) For assessing the risk of cardiovascular diseases;
- (v) For use in diabetes management;
- (vi) For identifying or inferring the identity of a microorganism directly from clinical material;
- (vii) 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;
- (viii) For noninvasive testing; and
- (ix) For near patient testing (point of care).

16. Section 866.3060 is amended by revising paragraph (b) to read as follows:

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

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

17. Section 866.3085 is amended by revising paragraph (b) to read as follows:

§ 866.3060 Blastomyces dermatitidis serological reagents.

* * * * *

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

17. Section 866.3085 is amended by revising paragraph (b) to read as follows:

§ 866.3085 Brucella spp. serological reagents.

* * * * *

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

18. Section 866.3135 is amended by revising paragraph (b) to read as follows:

§ 866.3135 Coccidioides immitis serological reagents.

* * * * *

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

19. Section 866.3165 is amended by revising paragraph (b) to read as follows:

§ 866.3165 Cryptococcus neoformans serological reagents.

* * * * *

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

20. Section 866.3220 is amended by revising paragraph (b) to read as follows:

§ 866.3220 Entamoeba histolytica serological reagents.

* * * * *

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

21. Section 866.3280 is amended by revising paragraph (b) to read as follows:

§ 866.3280 Francisella tularensis serological reagents.

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

22. Section 866.3300 is amended by revising paragraph (b) to read as follows:

§ 866.3300 Haemophilus spp. serological reagents.

* * * * *

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

23. Section 866.3320 is amended by revising paragraph (b) to read as follows:

§ 866.3320 Histoplasma capsulatum serological reagents.

* * * * *

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

24. Section 866.3350 is amended by revising paragraph (b) to read as follows:

§ 866.3350 Leptospira spp. serological reagents.

* * * * *

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

25. Section 866.3415 is amended by revising paragraph (b) to read as follows:

§ 866.3415 Pseudomonas spp. serological reagents.

* * * * *

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

26. Section 866.3550 is amended by revising paragraph (b) to read as follows:

§ 866.3550 Salmonella spp. serological reagents.

* * * * *

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

27. Section 866.3660 is amended by revising paragraph (b) to read as follows:

§ 866.3660 Shigella spp. serological reagents.

* * * * *

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

28. Section 866.3930 is amended by revising paragraph (b) to read as follows:

§ 866.3930 Vibrio cholerae serological reagents.

* * * * *

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

29. Section 866.5040 is amended by revising paragraph (b) to read as follows:

§ 866.5040 Albumin immunological test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

30. Section 866.5320 is amended by revising paragraph (b) to read as follows:

§ 866.5320 Properdin factor B immunological test system.

* * * * *

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

31. Section 866.5380 is amended by revising paragraph (b) to read as follows:

§ 866.5380 Free secretory component immunological test system.

* * * * *

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

32. Section 866.5460 is amended by revising paragraph (b) to read as follows:

§ 866.5460 Haptoglobin immunological test system.

* * * * *

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

33. Section 866.5490 is amended by revising paragraph (b) to read as follows:

§ 866.5490 Hemopexin immunological test system.

* * * * *

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

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

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

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

35. Section 876.9 is amended by designating the introductory text as paragraph (a), by redesignating paragraphs (a) and (b) as paragraphs (a)(1) and (a)(2), respectively, and by adding new paragraph (b) to read as follows:

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

* * * * *

(b) The exemption from the requirement of premarket notification for a generic type of class II device

applies only to those class II devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. A class II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification when:

(1) 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

(2) 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

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

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

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

(iii) 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;

(iv) For assessing the risk of cardiovascular diseases;

(v) For use in diabetes management;

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

(vii) For detection of antibodies to microorganism 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;

(viii) For noninvasive testing; and

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

36. Section 876.1620 is amended by revising paragraph (b) to read as follows:

§ 876.1620 Urodynamics measurement system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

37. Section 876.1800 is amended by revising paragraph (b) to read as follows:

§ 876.1800 Urine flow or volume measuring system.

* * * * *

(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 § 876.9.

* * * * *

38. Section 876.2040 is amended by revising paragraph (b)(1) to read as follows:

§ 876.2040 Enuresis alarm.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

39. Section 876.4370 is amended by revising paragraph (b)(1) to read as follows:

§ 876.4370 Gastroenterology-urology evacuator.

* * * * *

(b) *Classification.* (1) Class II (special controls) for the gastroenterology-urology evacuator when other than manually powered. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

* * * * *

40. Section 876.4650 is amended by revising paragraph (b) to read as follows:

§ 876.4650 Water jet renal stone dislodger system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

41. Section 876.4680 is amended by revising paragraph (b) to read as follows:

§ 876.4680 Ureteral stone dislodger.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

42. Section 876.4890 is amended by revising paragraph (b)(1) to read as follows:

§ 876.4890 Urological table and accessories.

* * * * *

(b) *Classification.* (1) Class II (special controls) for the electrically powered urological table and accessories. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

* * * * *

43. Section 876.5250 is amended by revising paragraph (b)(1) to read as follows:

§ 876.5250 Urine collector and accessories.

* * * * *

(b) *Classification.* (1) Class II (special controls) for a urine collector and accessories intended to be connected to an indwelling catheter. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

* * * * *

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

44. The authority citation for 21 CFR 880 continues to read as follows:

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

45. Section 880.9 is amended by designating the introductory text as paragraph (a), by redesignating paragraphs (a) and (b) as paragraphs (a)(1) and (a)(2), respectively, and by adding new paragraph (b) to read as follows:

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

* * * * *

(b) The exemption from the requirement of premarket notification for a generic type of class II device applies only to those class II devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. A class II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification when:

(1) 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

(2) 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

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

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

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

(iii) 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;

(iv) For assessing the risk of cardiovascular diseases;

(v) For use in diabetes management;

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

(vii) 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;

(viii) For noninvasive testing; and

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

46. Section 880.2200 is amended by revising paragraph (b) to read as follows:

§ 880.2200 Liquid crystal forehead temperature strip.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

47. Section 880.2920 is amended by revising paragraph (b) to read follows:

§ 880.2920 Clinical mercury thermometer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

48. Section 880.5100 is amended by revising paragraph (b) to read as follows:

§ 880.5100 AC-powered adjustable hospital bed.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

49. Section 880.5140 is amended by revising paragraph (b) to read as follows:

§ 880.5140 Pediatric hospital bed.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

50. Section 880.5475 is amended by revising paragraph (b) to read as follows:

§ 880.5475 Jet lavage.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

51. Section 880.5500 is amended by revising paragraph (b) to read as follows:

§ 880.5500 AC-powered patient lift.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

52. Section 880.5550 is amended by revising paragraph (b) to read as follows:

§ 880.5550 Alternating pressure air flotation mattress.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

53. Section 880.6740 is amended by revising paragraph (b) to read as follows:

§ 880.6740 Vacuum-powered body fluid suction apparatus.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

54. Section 880.6775 is amended by revising paragraph (b) to read as follows:

§ 880.6775 Powered patient transfer device.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

55. Section 880.6910 is amended by revising paragraph (b) to read as follows:

§ 880.6910 Wheeled stretcher.

* * * * *

(b) *Classification.* Class II (special 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

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

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

57. Section 882.9 is amended by designating the introductory text as paragraph (a), by redesignating paragraphs (a) and (b) as paragraphs (a)(1) and (a)(2), respectively, and by adding new paragraph (b) to read as follows:

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

* * * * *

(b) The exemption from the requirement of premarket notification for a generic type of class II device applies only to those class II devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. A class II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification when:

(1) 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

(2) 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

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

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

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

(iii) 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;

(iv) For assessing the risk of cardiovascular diseases;

(v) For use in diabetes management;

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

(vii) 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;

(viii) For noninvasive testing; and

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

58. Section 882.5050 is amended by revising paragraph (b) to read as follows:

§ 882.5050 Biofeedback device.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter when it is a prescription battery powered device that is indicated for relaxation training and muscle reeducation and prescription use, subject to § 882.9.

PART 886—OPHTHALMIC DEVICES

59. The authority citation 21 CFR Part 886 continues to read as follows:

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

60. Section 886.9 is amended by revising the section heading, by designating the introductory text as paragraph (a), by redesignating paragraphs (a) and (b) as paragraphs (a)(1) and (a)(2), respectively, and by adding new paragraph (b) to read as follows:

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

* * * * *

(b) The exemption from the requirement of premarket notification for a generic type of class II device applies only to those class II devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. A class II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification when:

(1) 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

(2) 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

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

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

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

(iii) 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;

(iv) For assessing the risk of cardiovascular diseases;

(v) For use in diabetes management;

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

(vii) 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;

(viii) For noninvasive testing; and

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

61. Section 886.3100 is amended by revising paragraph (b) to read as follows:

§ 886.3100 Ophthalmic tantalum clip.

* * * * *

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

62. Section 886.3130 is amended by revising paragraph (b) to read as follows:

§ 886.3130 Ophthalmic conformer.

* * * * *

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

63. Section 886.3800 is amended by revising paragraph (b) to read as follows:

§ 886.3800 Scleral shell.

* * * * *

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

PART 890—PHYSICAL MEDICINE DEVICES

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

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

65. Section 890.9 is amended by designating the introductory text as paragraph (a), by redesignating paragraphs (a) and (b) as paragraphs (a)(1) and (a)(2), respectively, and by adding new paragraph (b) to read as follows:

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

* * * * *

(b) The exemption from the requirement of premarket notification for a generic type of class II device applies only to those class II devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. A class II device for which FDA has granted an exemption from the requirement of

premarket notification must still submit a premarket notification when:

(1) 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

(2) 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

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

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

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

(iii) 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;

(iv) For assessing the risk of cardiovascular diseases;

(v) For use in diabetes management;

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

(vii) 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;

(viii) For noninvasive testing; and

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

66. Section 890.1925 is amended by revising paragraph (b) to read as follows:

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

67. Section 890.3500 is amended by revising paragraph (b) to read as follows:

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

68. Section 890.1925 is amended by revising paragraph (b) to read as follows:

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

69. Section 890.1925 is amended by revising paragraph (b) to read as follows:

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

§ 890.1925 Isokinetic testing and evaluation system.

* * * * *

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

67. Section 890.3500 is amended by revising paragraph (b) to read as follows:

§ 890.3500 External assembled lower limb prosthesis.

* * * * *

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

68. Section 890.3710 is amended by revising paragraph (b) to read as follows:

§ 890.3710 Powered communication system.

* * * * *

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

69. Section 890.3725 is amended by revising paragraph (b) to read as follows:

§ 890.3725 Powered environmental control system.

* * * * *

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

70. Section 890.5160 is amended by revising paragraph (b) to read as follows:

§ 890.5160 Air-fluidized bed.

* * * * *

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

71. Section 890.5170 is amended by revising paragraph (b) to read as follows:

§ 890.5170 Powered flotation therapy bed.

* * * * *

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

72. Section 890.5225 is amended by revising paragraph (b) to read as follows:

§ 890.5225 Powered patient rotation bed.

* * * * *

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

73. Section 890.5720 is amended by revising paragraph (b) to read as follows:

§ 890.5720 Water circulating hot or cold pack.

* * * * *

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

74. Section 890.5740 is amended by revising paragraph (b) to read as follows:

§ 890.5740 Powered heating pad.

* * * * *

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

PART 892—RADIOLOGY DEVICES

75. The authority citation for 21 CFR part 892 continues to read as follows:

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

76. Section 892.9 is amended by designating the introductory text as paragraph (a), by redesignating paragraphs (a) and (b) as paragraphs (a)(1) and (a)(2), respectively, and by adding new paragraph (b) to read as follows:

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

* * * * *

(b) The exemption from the requirement of premarket notification for a generic type of class II device applies only to those class II devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. A class II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification when:

(1) 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

(2) 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

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

(i) For use in the diagnosis, monitoring, or screening of neoplastic

diseases with the exception of immunohistochemical devices;

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

(iii) 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;

(iv) For assessing the risk of cardiovascular diseases;

(v) For use in diabetes management;

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

(vii) 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;

(viii) For noninvasive testing; and

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

77. Section 892.1980 is amended by revising paragraph (b) to read as follows:

§ 892.1980 Radiologic table.

* * * * *

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

Dated: October 22, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-29189 Filed 11-2-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF DEFENSE**Office of the Secretary****32 CFR Part 199**

RIN 0720-AA42

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); State Victims of Crime Compensation Programs; Voice Prosthesis

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This final rule establishes CHAMPUS as primary payer to State Victims of Crime Compensation Programs; and voice prostheses as a CHAMPUS benefit.

EFFECTIVE DATES: Amendments to §§ 199.2 and 199.8 are effective