

Food and Drug Administration, HHS

§ 864.1

- 864.7360 Erythrocytic glucose-6-phosphate dehydrogenase assay.
- 864.7375 Glutathione reductase assay.
- 864.7400 Hemoglobin A₂ assay.
- 864.7415 Abnormal hemoglobin assay.
- 864.7425 Carboxyhemoglobin assay.
- 864.7440 Electrophoretic hemoglobin analysis system.
- 864.7455 Fetal hemoglobin assay.
- 864.7470 Glycosylated hemoglobin assay.
- 864.7490 Sulfhemoglobin assay.
- 864.7500 Whole blood hemoglobin assays.
- 864.7525 Heparin assay.
- 864.7660 Leukocyte alkaline phosphatase test.
- 864.7675 Leukocyte peroxidase test.
- 864.7695 Platelet factor 4 radioimmunoassay.
- 864.7720 Prothrombin consumption test.
- 864.7735 Prothrombin-proconvertin test and thrombotest.
- 864.7750 Prothrombin time test.
- 864.7825 Sickle cell test.
- 864.7875 Thrombin time test.
- 864.7900 Thromboplastin generation test.
- 864.7925 Partial thromboplastin time tests.
- 864.9275 Blood bank centrifuge for in vitro diagnostic use.
- 864.9285 Automated cell-washing centrifuge for immuno-hematology.
- 864.9300 Automated Coombs test systems.
- 864.9320 Copper sulfate solution for specific gravity determinations.
- 864.9400 Stabilized enzyme solution.
- 864.9550 Lectins and protectins.
- 864.9575 Environmental chamber for storage of platelet concentrate.
- 864.9600 Potentiating media for in vitro diagnostic use.
- 864.9650 Quality control kit for blood banking reagents.
- 864.9700 Blood storage refrigerator and blood storage freezer.
- 864.9750 Heat-sealing device.
- 864.9875 Transfer set.

Subpart K—Products Used In Establishments That Manufacture Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

- 864.9900 Cord blood processing system and storage container.

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

EDITORIAL NOTE: Nomenclature changes to part 864 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 864.1 Scope.

(a) This part sets forth the classification of hematology and pathology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(d) Guidance documents referenced in this part are available on the Internet

Subpart I—Hematology Reagents

- 864.8100 Bothrops atrox reagent.
- 864.8150 Calibrator for cell indices.
- 864.8165 Calibrator for hemoglobin or hematocrit measurement.
- 864.8175 Calibrator for platelet counting.
- 864.8185 Calibrator for red cell and white cell counting.
- 864.8200 Blood cell diluent.
- 864.8500 Lymphocyte separation medium.
- 864.8540 Red cell lysing reagent.
- 864.8625 Hematology quality control mixture.
- 864.8950 Russell viper venom reagent.

Subpart J—Products Used In Establishments That Manufacture Blood and Blood Products

- 864.9050 Blood bank supplies.
- 864.9100 Empty container for the collection and processing of blood and blood components.
- 864.9125 Vacuum-assisted blood collection system.
- 864.9145 Processing system for frozen blood.
- 864.9160 Blood group substances of nonhuman origin for in vitro diagnostic use.
- 864.9175 Automated blood grouping and antibody test system.
- 864.9185 Blood grouping view box.
- 864.9195 Blood mixing devices and blood weighing devices.
- 864.9205 Blood and plasma warming device.
- 864.9225 Cell-freezing apparatus and reagents for in vitro diagnostic use.
- 864.9245 Automated blood cell separator.

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at <http://www.fda.gov/cdrh/guidance.html>.

[52 FR 17732, May 11, 1987, as amended at 69 FR 12273, Mar. 16, 2004]

§ 864.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section

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513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

[52 FR 17732, May 11, 1987]

§ 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).

[65 FR 2310, Jan. 14, 2000]

Subpart B—Biological Stains

§ 864.1850 Dye and chemical solution stains.

(a) *Identification.* Dye and chemical solution stains for medical purposes are mixtures of synthetic or natural dyes or nondye chemicals in solutions used in staining cells and tissues for diagnostic histopathology, cytopathology, or hematology.

(b) *Classification.* Class I (general controls). These devices are exempt from the premarket notification procedures

in subpart E of part 807 of this chapter subject to the limitations in § 864.9. These devices are also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 60583, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989; 66 FR 38789, July 25, 2001]

§ 864.1860 Immunohistochemistry reagents and kits.

(a) *Identification.* Immunohistochemistry test systems (IHC's) are in vitro diagnostic devices consisting of polyclonal or monoclonal antibodies labeled with directions for use and performance claims, which may be packaged with ancillary reagents in kits. Their intended use is to identify, by immunological techniques, antigens in tissues or cytologic specimens. Similar devices intended for use with flow cytometry devices are not considered IHC's.

(b) *Classification of immunohistochemistry devices.* (1) Class I (general controls). Except as described in paragraphs (b)(2) and (b)(3) of this section, these devices are exempt from the premarket notification requirements in part 807, subpart E of this chapter. This exemption applies to IHC's that provide the pathologist with adjunctive diagnostic information that may be incorporated into the pathologist's report, but that is not ordinarily reported to the clinician as an independent finding. These IHC's are used after the primary diagnosis of tumor (neoplasm) has been made by conventional histopathology using nonimmunologic histochemical stains, such as hematoxylin and eosin. Examples of class I IHC's are differentiation markers that are used as adjunctive tests to subclassify tumors, such as keratin.

(2) Class II (special control, guidance document: "FDA Guidance for Submission of Immunohistochemistry Applications to the FDA," Center for Devices and Radiologic Health, 1998). These IHC's are intended for the detection and/or measurement of certain