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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 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 (*insert date 30 days after date of publication in the Federal Register*).

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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, 1997, 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 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 immunoassay 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) to incorporate 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)(l) 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 on 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 the premarket notification exemptions for each generic 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 procedures 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(i) 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 “interlabial” is more appropriate than the term “intralabial” and is using the term “interlabial” 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 868.5830) and is subject to premarket notification requirements.

3. One comment requested clarification about how the “Limitations to exemption” apply to a device labeled for general use, such as 21 CFR 862.2300 ***Colorimeter, photometer, or spectrophotometer for clinical use*** or 21 CFR 862.2560 ***Fluorometer for clinical use***. Section 862.9(c) states the exemption from 510(k) of the act does not apply if the device is intended, “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.”

The ‘ ‘Limitations to exemption’ ’ refer to the device, as labeled. If the device has been labeled as a general purpose device, and was exempt, and it is now to be labeled for a specific indication, such as cytomegalovirus, a new 510(k) must be submitted and cleared before that specific indication can be marketed.

4. One comment regarding the “Limitations to exemption” objected to the revocation of the premarket notification exemption for the cardiopulmonary bypass accessory equipment involving an electrical connection to the patient prior to up-classifying them into class II in order to comply

with the performance standard for cables and leads. The comment stated that many of the cardiopulmonary bypass devices did not involve a cable or lead.

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. Because FDA believes that compliance with the performance standard for electrode lead wires and patient cables would provide adequate assurance of the safety and effectiveness of these devices, the proposal provides that these devices would be exempt from the premarket notification requirements.

Elsewhere in this issue of the **Federal Register**, FDA is announcing that it is withdrawing the proposed rules to revoke the exemptions from premarket notification for cardiopulmonary bypass accessory equipment and the electrode cable. Under existing 21 CFR 870.4200 (cardiopulmonary bypass accessory equipment) and 21 CFR 890.1175 (electrode cable), these devices are exempt from the premarket notification requirements. These exemptions will remain in effect. FDA expects to finalize the August 9, 1999, proposed rule to make these devices class II shortly after the comment period ends on November 8, 1999. If the rule is finalized, the devices will be exempt from the premarket notification requirements and all such devices will be subject to the performance standard for electrode lead wires and patient cables, when the second phase of that rule becomes effective on May 9, 2000. FDA believes that there is no reason to make these devices subject to **premarket notification** requirements for the short period of time between the revocation of the exemption from premarket notification requirements, as proposed in the

November 12, 1998, **Federal Register**, and the reclassification and exemption from premarket notification requirements of these devices, as proposed in the August 9, 1999, **Federal Register**.

The goniometer device is not a subject of this rule and premarket notification is still required for these devices under existing 21 CFR 888.1500, until the August 9, 1999, rule is finalized.

5. FDA, on its own initiative, is adding all versions of the keratoscope (21 CFR 886.1350) to the list of devices exempt from premarket notification requirements. Previously, only keratoscopes that did not include computer software were exempt from premarket notification. In **the Federal Register** of February 2, 1998 (63 FR 5387), FDA listed a keratoscope with computer software, as a device that it believed fell under the exemption criteria in section 510(l) of the act. 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(k) 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.” (Emphasis added.) The proposed rule may have been interpreted to require premarket notification for only devices that were used in screening or diagnosis of both familial and acquired genetic disorders.

FDA intended that devices used in connection with either familial or acquired genetic disorders be subject to premarket notification requirements because misdiagnosis of either of these disorders would be associated with high morbidity or mortality. Accordingly, FDA has amended the final rule in each limitation section of each classification regulation to state 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 or acquired genetic disorders, including inborn errors of metabolism.” (Emphasis added.)

Similarly, FDA stated in the proposed limitation in paragraph (c)(7) that it would 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.

For example, proposed § **880.5090 Liquid bandage** stated: “When used as a skin protectant, the device is exempt from premarket notification procedures.” FDA amended final § 880.5090 by adding the word “only” to the text to clarify that if the device were intended for a use in addition to protecting skin, it would not qualify for the exemption. Accordingly, final § 880.5090 states: “When used *only* as a skin protectant, the device is exempt from premarket notification procedures.” Similarly, FDA has amended final §§ **886.4070 Powered cornea2 burr** and **886.4750 Ophthalmic eye shield** by adding the word “only” to clarify the exemption does not apply when the device is used for intended uses not specifically stated in the regulation.

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 I-DESIGNATIONS OF RESERVED CLASS I DEVICES

21 CFR Section	Name of Device
862.1065	Ammonia test system
862.1113	Bilirubin (total and unbound) in the neonate test system
862.1310	Galactose test system
862.1410	Iron (non-heme) test system
862.1415	Iron-binding capacity test system
862.1495	Magnesium test system
862.1580	Phosphorous (inorganic) test system
862.1660	Quality control material (assayed and unassayed) ¹
862.1680	Testosterone test system
862.1730	Free tyrosine test system
862.1775	Uric acid test system
862.3050	Breath-alcohol test system
862.3110	Antimony test system
862.3120	Arsenic test system
862.3220	Carbon monoxide test system
862.3240	Cholinesterase test system
862.3280	Clinical toxicology control material (assayed and unassayed) ¹
862.3600	Mercury test system
862.3750	Quinine test system

TABLE 1—DESIGNATIONS OF RESERVED CLASS I DEVICES—Continued

21 CFR Section	Name of Device
862.3850	Sulfonamide test system
864.7040	Adenosine triphosphate release assay
864.8950	Russell viper venom reagent
864.9050	Blood bank supplies
864.9125	Vacuum-assisted blood collection system ²
864.9195	Blood mixing devices and blood weighing devices ²
866.2390	Transport culture medium
866.2560	Microbial growth monitor ³
866.2850	Automated zone reader
866.2900	Microbiological specimen collection and transport device
866.3110	Campylobacter fetus serological reagents
866.3120	Chlamydia serological reagents
866.3235	Epstein-Barr virus serological reagents
866.3370	Mycobacterium tuberculosis immunofluorescent reagents
866.3870	Trypanosoma spp. serological reagents
872.3700	Dental mercury
872.4200	Dental handpiece and accessories
872.6250	Dental chair and accessories ⁴
872.6640	Dental operative unit and accessories ⁵
872.6710	Boiling water sterilizer
876.5160	Urological clamps for males ⁶
878.4460	Surgeon's glove
880.5090	Liquid bandage ⁷
880.5680	Pediatric position holder
880.6250	Patient examination glove
880.6375	Patient lubricant
880.6760	Protective restraint
882.1030	Ataxiagraph
882.1420	Electroencephalogram (EEG) signal spectrum analyzer
882.4060	Ventricular cannula ⁸
882.4545	Shunt system implantation instrument ⁹
884.2980(a)	Telethermographic system ¹⁰
884.2982(a)	Liquid crystal thermographic system ¹¹
884.5435	Unscented menstrual pads (interlabial pads and reusable menstrual pads)
886.4070	Powered corneal burr ¹²
886.4300	Intraocular lens guide ¹³
886.4370	Keratome
886.4750	Ophthalmic eye shield (when made of other than plastic or aluminum)
888.1500	Goniometer
890.3850	Mechanical wheelchair
890.5710	Hot or cold disposable pack ¹⁴
892.1100	Scintillation (gamma) camera
892.1110	Positron camera

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

21 CFR Section	Name of Device
862.1030	Alanine amino transferase (ALT/SGPT) test system
862.1040	Aldolase test system
862.1060	Delta-aminolevulinic acid test system
862.1075	Androstenedione test system
862.1080	Androsterone test system
862.1095	Ascorbic acid test system
862.1115	Urinary bilirubin and its conjugates (nonquantitative) test system
862.1130	Blood volume test system
862.1135	C-peptides of proinsulin test system
862.1165	Catecholamines (total) test system
862.1175	Cholesterol (total) test
862.1180	Chymotrypsin test system
862.1185	Compound S (11-deoxycortisol) test system
862.1195	Corticoids test system
862.1200	Corticosterone test system
862.1240	Cystine test system
862.1245	Dehydroepiandrosterone (free and sulfate) test system
862.1250	Desoxycorticosterone test system
862.1260	Estradiol test system
862.1265	Estriol test system
862.1270	Estrogens (total, in pregnancy) test system
862.1275	Estrogens (total, nonpregnancy) test system
862.1280	Estrone test system
862.1285	Etiocolanalone test system
862.1300	Follicle-stimulating hormone test system
862.1325	Gastrin test system
862.1330	Globulin test system
862.1335	Glucagon test system
862.1360	Gamma-glutamyl transpeptidase and isoenzymes test system
862.1370	Human growth hormone test system
862.1375	Histidine test system
862.1385	17-Hydroxycorticosteroids (17-ketogenic steroids) test system
862.1390	5-Hydroxyindole acetic acid/serotonin test system
862.1395	17-Hydroxyprogesterone test system
862.1400	Hydroxyproline test system
862.1405	Immunoreactive insulin test system
862.1430	17-Ketosteroids test system
862.1435	Ketones (nonquantitative) test system
862.1450	Lactic acid test system
862.1460	Leucine aminopeptidase test system
862.1465	Lipase test system
862.1475	Lipoprotein test system
862.1485	Luteinizing hormone test system
862.1500	Malic dehydrogenase test system
862.1505	Mucopolysaccharides (nonquantitative) test system
862.1510	Nitrite (nonquantitative) test system
862.1520	5'-Nucleotidase test system
862.1530	Plasma oncometry test system
862.1535	Ornithine carbamyl transferase test system
862.1540	Osmolality test system
862.1542	Oxalate test system
862.1550	Urinary pH (nonquantitative) test system
862.1560	Urinary phenylketones (nonquantitative) test system
862.1570	Phosphohexose isomerase test system
862.1590	Porphobilinogen test system
862.1595	Porphyrins test system
862.1605	Pregnanediol test system
862.1610	Pregnanetriol test system
862.1615	Pregnenolone test system
862.1620	Progesterone test system
862.1625	Prolactin (lactogen) test system
862.1630	Protein (fractionation) test system
862.1645	Urinary protein or albumin (nonquantitative) test system
862.1650	Pyruvate kinase test system
862.1655	Pyruvic acid test system
862.1660	Quality control material (assayed and unassayed) ¹
862.1705	Triglyceride test system
862.1725	Trypsin test system
862.1780	Urinary calculi (stones) test system
862.1785	Urinary urobilinogen (nonquantitative) test system
862.1790	Uroporphyrin test system
862.1795	Vanilmandelic acid test system

TABLE 2—DESIGNATIONS OF EXEMPTED CLASS I DEVICES-Continued

21 CFR Section	Name of Device
862.1805	Vitamin A test system
862.1820	Xylose test system
862.2140	Centrifugal chemistry analyzer for clinical use
862.2150	Continuous flow sequential multiple chemistry analyzer for clinical use
862.2160	Discrete photometric chemistry analyzer for clinical use
862.2170	Micro chemistry analyzer for clinical use
862.2250	Gas liquid chromatography system for clinical use
862.2260	High pressure liquid chromatography system for clinical use
862.2270	Thin-layer chromatography system for clinical use
862.2300	Colorimeter, photometer, or spectrophotometer for clinical use
862.2400	Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use
862.2500	Enzyme analyzer for clinical use
862.2540	Flame emission photometer for clinical use
862.2560	Fluorometer for clinical use
862.2680	Microtitrator for clinical use
862.2700	Nephelometer for clinical use
862.2730	Osmometer for clinical use
862.2750	Pipetting and diluting system for clinical use
862.2850	Atomic absorption spectrophotometer for clinical use
862.2860	Mass spectrometer for clinical use
862.2900	Automated urinalysis system
862.3280	Clinical toxicology control material (assayed and unassayed) ¹
864.2280	Cultured animal and human cells
864.3250	Specimen transport and storage container
864.5240	Automated blood cell diluting apparatus
864.6150	Capillary blood collection tube
864.9125	Vacuum-assisted blood collection system ²
864.9185	Blood grouping view box
864.9195	Blood mixing devices and blood weighing devices ²
864.9225	Cell-freezing apparatus and reagents for in vitro diagnostic use
864.9275	Blood bank centrifuge for in vitro diagnostic use
864.9320	Copper sulphate solution for specific gravity determinations
864.9750	Heat-sealing device
866.2660	Microorganism differentiation and identification device
866.3040	Aspergillus spp. serological reagents
866.3140	Corynebacterium spp. serological reagents
866.3145	Coxsackievirus serological reagents
866.3200	Echinococcus spp. serological reagents
866.3240	Equine encephalomyelitis virus serological reagents
866.3355	Listeria spp. serological reagents
866.3360	Lymphocytic choriomeningitis virus serological reagents
866.3375	Mycoplasma spp. serological reagents
866.3380	Mumps virus serological reagents
866.3405	Moliovirus serological reagents
866.3480	Respiratory syncytial virus serological reagents
866.3500	Rickettsia serological reagents
866.3600	Schistosoma spp. serological reagents
866.3680	Sporothrix schenckii serological reagents
866.3740	Streptococcus spp. serological reagents
866.3850	Trichinella spiralis serological reagents
866.5060	² albumin immunological test system
866.5065	Human allotypic marker immunological test system
866.5160	³ eta-globulin immunological test system
866.5200	² arbonic anhydrase B and C immunological test system
866.5330	² actor XIII, A, S, immunological test system ³
866.5400	⁴ alpha-globulin immunological test system
866.5420	⁴ alpha-1-glycoproteins immunological test system
866.5425	⁴ alpha-2-glycoproteins immunological test system
866.5430	³ eta-2-glycoprotein I immunological test system
866.5440	³ eta-2-glycoprotein III immunological test system
866.5560	Lactate dehydrogenase immunological test system
866.5570	Lactoferrin immunological test system
866.5590	Lipoprotein X immunological test system
866.5715	² lasminogen immunological test system
866.5735	² rothrombin immunological test system ⁴
866.5765	Retinol-binding protein immunological test system
866.5890	Enter-alpha trypsin inhibitor immunological test system
868.1910	Esophageal stethoscope
868.5620	Breathing mouthpiece
868.5640	Medicinal nonventilatory nebulizer (atomizer)
868.5675	Rebreathing device
868.5700	Nonpowered oxygen tent

TABLE 2—DESIGNATIONS OF EXEMPTED CLASS I DEVICES-Continued

21 CFR Section	Name of Device
868.6810	Tracheobronchial suction catheter
872.3275(a)(1)	Dental cement (zinc oxide-eugenol)
872.3400(b)(1)	Karaya and sodium borate with or without acacia denture adhesive (less than 12 percent sodium borate by weight)
872.3540(b)(1)	OTC denture cushion or pad ⁵
872.6300	Rubber dam and accessories ⁶
872.6390	Dental floss
874.1070	Short increment sensitivity index (SIS) adapter
874.1100	Earphone cushion for audiometric testing
874.1500	Gustometer
874.1800	Air or water caloric stimulator
874.1925	Toynbee diagnostic tube
874.3300(b)(1)	Hearing aid ⁷
874.3540	Prosthesis modification instrument for ossicular replacement surgery
874.4100	Epistaxis balloon
874.4420	Ear, nose, and throat manual surgical instrument
874.5300	Ear, nose, and throat examination and treatment unit
874.5550	Powered nasal irrigator
874.5840	Antistammering device
876.5160	Urological clamp for males ⁸
876.5210	Enema kit
876.5250(b)(2)	Urine collector and accessories ⁹
876.5980(b)(2)	Gastrointestinal tube and accessories ¹⁰
878.3250	External facial fracture fixation appliance
878.3910	Inflatable extremity splint
878.3925	Elastic surgery kit and accessories
878.4040	Surgical apparel ¹¹
878.4100	Organ bag
878.4200	Introduction/drainage catheter and accessories
878.4320	Removable skin clip
878.4680	Nonpowered, single patient, portable suction apparatus
878.4760	Removable skin staple
878.4820	Surgical instrument motors and accessories/attachments
878.4960	Operating tables and accessories and operating chairs and accessories
880.5090	Liquid bandage ¹²
880.5270	Neonatal eye pad
880.5420	Pressure infuser for an I.V. bag
882.1200	Two-point discriminator
882.1500	Anesthesiometer
882.1750	Pinwheel
882.4060	Intracranial cannula ¹³
882.4545	Shunt system implantation instrument ¹⁴
882.4650	Neurosurgical suture needle
882.4750	Skull punch ¹⁵
884.1040	Rheometer for cervical mucus
886.1350	Retinoscope
886.1780	Retinoscope ¹⁶
886.1940	Thermometer sterilizer
886.4070	Powered corneal burr ¹⁷
886.4300	Intraocular lens guide ¹⁸
886.5850	Sunglasses (nonprescription)
890.5180	Manual patient rotation bed
890.5710	Hot or cold disposable pack ¹⁹
892.1300	Nuclear rectilinear scanner
892.1320	Nuclear uptake probe
892.1330	Nuclear whole body scanner
892.1350	Nuclear scanning bed
892.1410	Nuclear electrocardiograph synchronizer
892.1890	Radiographic film illuminator
892.1910	Radiographic grid
892.1960	Radiographic intensifying screen
892.1970	Radiographic ECG/respirator, synchronizer
892.2010	Medical image storage device
892.2020	Medical image communications device
892.5650	Manual radionuclide applicator system
892.6500	Personnel protective shield

¹ 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 21 CFR 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 uses 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.

¹⁸ Exemption does not apply if used as folders and injectors for soft or foldable IOL's.

¹⁹ Exemption does not apply if intended for use on infants

V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 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 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) (§ 886.4750).

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 Sulfonamide 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.

VI. 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, 868, 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, 878,880, 882, 884, 886, 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:

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

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 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:

9862.1115 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:

5862.1130 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 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.

13. Section 862.1175 is amended by revising paragraph (b) to read as follows:

§ 862.1175 Cholesterol (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.

14. Section 862.1180 is amended by revising paragraph (b) to read as follows:

§ 862.1180 Chymotrypsin 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.

15. Section 862.1185 is amended by revising paragraph (b) to read as follows:

§ 862.1185 Compound S (1 1-deoxycortisol) 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.

16. Section 862.1195 is amended by revising paragraph (b) to read as follows:

5862.1195 Corticoids 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.

17. Section 862.1200 is amended by revising paragraph (b) to read as follows:

§ 862.1200 Corticosterone 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.

18. Section 862.1240 is amended by revising paragraph (b) to read as follows:

§ 862.1240 Cystine 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.

19. Section 862.1245 is amended by revising paragraph (b) to read as follows:

§ 862.1245 Dehydroepiandrosterone (free and sulfate) 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.

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:

5862.1260 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:

5862.1265 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:

5862.1280 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 Etiocholanolone 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:

5862.1360 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 862.1385 is amended by revising paragraph (b) to read as follows:

§ 862.1385 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 862.1450 is amended by revising paragraph (b) to read as follows:

§ 862.1450 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:

§ 862.1505 Mucopolysaccharides (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 862.1510 is amended by revising paragraph (b) to read as follows:

§ 862.1510 Nitrite (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.

49. Section 862.1520 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.

50. 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.

51. 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.

52. 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.

53. Section 862.1542 is amended by revising paragraph (b) to read as follows:

§ 862.1542 Oxalate 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 862.1550 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.

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

5862.1560 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.

56. 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.

57. Section 862.1590 is amended by revising paragraph (b) to read as follows:

§ 862.1590 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.

58. Section 862.1595 is amended by revising paragraph (b) to read as follows:

§ 862.1595 Porphyrins 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.

59. Section 862.1605 is amended by revising paragraph (b) to read as follows:

§ 862.1605 Pregnanediol 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.

60. Section 862.1610 is amended by revising paragraph (b) to read as follows:

5862.1610 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.

61. Section 862.1615 is amended by revising paragraph (b) to read as follows:

5862.1615 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.

62. Section 862.1620 is amended by revising paragraph (b) to read as follows:

§ 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.

63. Section 862.1625 is amended by revising paragraph (b) to read as follows:

§ 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.

64. Section 862.1630 is amended by revising paragraph (b) to read as follows:

§ 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.

65. Section 862.1645 is amended by revising paragraph (b) to read as follows:

§ 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.

66. Section 862.1650 is amended by revising paragraph (b) to read as follows:

§ 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.

67. Section 862.1655 is amended by revising paragraph (b) to read as follows:

§ 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.

68. Section 862.1660 is amended by revising paragraph (b) to read as follows:

5862.1660 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.

69. Section 862.1705 is amended by revising paragraph (b) to read as follows:

§ 862.1705 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.

70. Section 862.1725 is amended by revising paragraph (b) to read as follows:

§ 862.1725 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.

71. Section 862.1780 is amended by revising paragraph (b) to read as follows:

§ 862.1780 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.

72. Section 862.1785 is amended by revising paragraph (b) to read as follows:

§ 862.1785 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.

73. Section 862.1790 is amended by revising paragraph (b) to read as follows:

§ 862.1790 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.

74. Section 862.1795 is amended by revising paragraph (b) to read as follows:

§ 862.1795 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.

75. Section 862.1805 is amended by revising paragraph (b) to read as follows:

§ 862.1805 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.

76. Section 862.1820 is amended by revising paragraph (b) to read as follows:

§ 862.1820 . 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.

77. Section 862.2140 is amended by revising paragraph (b) to read as follows:

§ 862.2140 Centrifugal 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.

78. Section 862.2150 is amended by revising paragraph (b) to read as follows:

§ 862.2150 Continuous flow sequential multiple 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.

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 Microtitrator 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:

§ 862.3750 Quinine test system.

* * * * *

(b) *Classification.* Class I.

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

§ 862.3850 Sulfonamide test system.

* * * * *

(b) *Classification.* Class I.

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

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

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

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). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

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). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9. 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.

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). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

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). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

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). The manual device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

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). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

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). The manual device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

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). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

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). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

110. Section 864.9320 is amended by revising paragraph (b) to read as follows:

§ 864.9320 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:

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

113. Section 866.9 is revised to read as follows:

5866.9 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).

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 Coxsackievirus 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.

123. Section 866.3380 is amended by revising paragraph (b) to read as follows:

§ 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 866.3405 is amended by revising paragraph (b) to read as follows:

§ 866.3405 Poliovirus 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:

§ 866.3504 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 schenckii serological reagents.

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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 § 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.

130. Section 866.3850 is amended by revising paragraph (b) to read as follows:

§ 866.3850 Trichinella spiralis 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 866.5060 is amended by revising paragraph (b) to read as follows:

§ 866.5060 Prealbumin 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.

132. Section 866.5065 is amended by revising paragraph (b) to read as follows:

§ 866.5065 Human allotypic marker 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.

133. Section 866.5160 is amended by revising paragraph (b) to read as follows:

§ 866.5160 Beta-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.

134. Section 866.5200 is amended by revising paragraph (b) to read as follows:

§ 866.5200 Carbonic anhydrase B and C immunological test system.

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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 § 866.9.

135. Section 866.5330 is amended by revising paragraph (b) to read as follows:

§ 866.5330 Factor XIII, A, S, 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. This exemption does not apply to factor deficiency tests classified under § 864.7290 of this chapter.

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-I -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.

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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 § 866.9.

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

§ 866.5440 Beta-2-glycoprotein III 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:

§ 866.5570 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 866.57 15 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 8665735 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. This exemption does not apply to multipurpose systems for in vitro coagulation studies classified under § 864.5425 of this chapter or prothrombin time tests classified under § 864.7750 of this chapter.

146. Section 866.2765 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:

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

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 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).

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.

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

§ 862.5620 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 1 (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:

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

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;

(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:

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

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;

(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:

§ 072.3275 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:

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

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 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).

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 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.

171. Section 874.1800 is amended by revising paragraph (b) to read as follows:

§ 874.1800 Air or water caloric stimulator.

* * * * *

(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.

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

§ 874.1925 Toyn bee 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:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 3601, 371.

18 1. 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;

(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).

182. Section 876.5 160 is amended by revising paragraph (b) to read as follows:

§ 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:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 3601,371.

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 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 no: 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.

191. Section 878.4040 is amended by revising paragraph (b) to read as follows:

§ 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.

* * * * *

(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.

198. Section 878.4960 is amended by revising paragraph (b) to read as follows:

§ 878.4960 Operating tables and accessories and operating chairs 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.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

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

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

200. Section 880.9 is revised to read as follows:

§ 880.9 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 § 8 12.3(k) of this chapter; and

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

201. Section 880.5090 is amended by revising paragraph (b) to read as follows:

§ 880.5090 Liquid bandage.

* * * * *

(b) **Classification.** Class I (general controls). When used only as a skin protectant, the device is exempt from the **premarket** notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

202. Section 880.5270 is amended by revising paragraph (b) to read as follows:

§ 880.5270 Neonatal eye pad.

* * * * *

(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. 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.

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:

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

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:

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

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.

* * * * *

(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 §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 21 CFR part 886 continues to read as follows:

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

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., 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).

219. Section 886.1350 is amended by revising paragraph (b) to read as follows:

§ 886.1350 Keratoscope.

* * * * *

(b) 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 § 820.198 of this chapter, with respect to complaint files

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

§ 886.1780 Retindscope.

* * * * *

(b) **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 886.1940 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 devices 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.

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. 35 l, 360, 360c, 360e, 360j, 37 l.

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).

PAR-f 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, 360e, 360j, 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;

(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 § 8 12.3(k) of this chapter; and

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

230. Section 890.5 180 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.

23 1. Section 890.57 10 is amended by revising paragraph (b) to read as follows:

§ 890.5710 Hot or cold disposable pack.

* * * * *

(b) *Classification.* Class I (general controls). Except when intended for use on infants, 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 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).

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.

238. Section 892.1410 is amended by revising paragraph (b) to read as follows:

§892.1410 Nuclear electrocardiograph synchronizer.

* * * * *

(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.

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

§ 892.1890 Radiographic film illuminator.

* * * * *

(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:

5892.1910 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:

§ 892.1970 Radiographic ECG/respirator synchronizer.

* * * * *

(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.

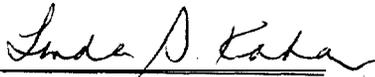
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(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.

Dated: 12/22/99

December 22, 1999



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jt [FR Doc. ⁰⁰~~99~~-⁰⁰???? Filed ??-??-⁰⁰~~99~~; 8:45 am]

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