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).
FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-I 190.

SUPPLEMENTARY INFORMATION:

1. 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 Resident 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(l) of the act. FDA received four comments in response to the proposed rule. The following is FDA’s response to those comments.

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

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

The 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), the 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>
<thead>
<tr>
<th>21 CFR Section</th>
<th>Name of Device</th>
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<tbody>
<tr>
<td>862.1065</td>
<td>Ammonia test system</td>
</tr>
<tr>
<td>862.1113</td>
<td>Bilirubin (total and unbound) in the neonate test system</td>
</tr>
<tr>
<td>862.1310</td>
<td>Galactose test system</td>
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<tr>
<td>862.1410</td>
<td>Iron (non-heme) test system</td>
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<tr>
<td>862.1415</td>
<td>Iron-binding capacity test system</td>
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<tr>
<td>862.1495</td>
<td>Magnesium test system</td>
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<tr>
<td>862.1580</td>
<td>Phosphorous (inorganic) test system</td>
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<tr>
<td>862.1660</td>
<td>Quality control material (assayed and unassayed)</td>
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<tr>
<td>862.1680</td>
<td>Testosterone test system</td>
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<tr>
<td>862.1730</td>
<td>Free tyrosine test system</td>
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<tr>
<td>862.1775</td>
<td>Uric acid test system</td>
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<tr>
<td>862.3050</td>
<td>Breath-alcohol test system</td>
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<tr>
<td>862.3110</td>
<td>Antimony test system</td>
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<tr>
<td>862.3120</td>
<td>Arsenic test system</td>
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<tr>
<td>862.3220</td>
<td>Carbon monoxide test system</td>
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<td>862.3240</td>
<td>Cholinesterase test system</td>
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<tr>
<td>862.3280</td>
<td>Clinical toxicology control material (assayed and unassayed)</td>
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<tr>
<td>862.3900</td>
<td>Mercury test system</td>
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<tr>
<td>862.3750</td>
<td>Quinine test system</td>
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FDA is amending the regulations to designate the following devices as exempt from premarket notification because FDA believes that they do not meet the reserved criteria under new section 510(l) of the act:
TABLE 2—DESIGNATIONS OF EXEMPTED CLASS I DEVICES

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>Name of Device</th>
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<tbody>
<tr>
<td>862.1030</td>
<td>Alanine aminotransferase (ALT/SGPT) test system</td>
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<tr>
<td>862.1040</td>
<td>Aldolase test system</td>
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<td>862.1060</td>
<td>Delta-aminolevulinic acid test system</td>
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<td>862.1075</td>
<td>Androstenedione test system</td>
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<td>862.1080</td>
<td>Androsterone test system</td>
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<td>862.1095</td>
<td>Ascorbic acid test system</td>
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<tr>
<td>862.1115</td>
<td>Urinary bilirubin and its conjugates (nonquantitative) test system</td>
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<td>862.1130</td>
<td>Blood volume test system</td>
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<tr>
<td>862.1135</td>
<td>C-peptides of proinsulin test system</td>
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<td>862.1165</td>
<td>Catecholamines (total) test system</td>
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<td>862.1175</td>
<td>Cholesterol (total) test system</td>
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<td>862.1180</td>
<td>Chymotrypsin test system</td>
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<td>862.1185</td>
<td>Compound 5 (11-deoxy cortisol) test system</td>
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<td>862.1195</td>
<td>Corticotropin test system</td>
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<td>862.1200</td>
<td>Corticosterone test system</td>
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<td>Cystine test system</td>
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<td>862.1245</td>
<td>Dehydroepiandrosterone (free and sulfate) test system</td>
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<td>Desoxycorticosterone test system</td>
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<td>Estradiol test system</td>
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<td>Estriol test system</td>
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<td>862.1270</td>
<td>Estrogens (total, in pregnancy) test system</td>
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<td>862.1275</td>
<td>Estrogens (total, nonpregnancy) test system</td>
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<td>862.1280</td>
<td>Estrone test system</td>
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<td>862.1285</td>
<td>Etocholanocone test system</td>
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<td>862.1300</td>
<td>Follicle-stimulating hormone test system</td>
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<td>Gastrin test system</td>
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<td>Globulin test system</td>
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<td>862.1335</td>
<td>Glucagon test system</td>
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<td>862.1360</td>
<td>Gamma-glutamyl transpeptidase and isoenzymes test system</td>
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<td>862.1370</td>
<td>Human growth hormone test system</td>
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<td>862.1375</td>
<td>Histidine test system</td>
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<tr>
<td>862.1385</td>
<td>17-Hydroxy cortisol steroids (17-ketogenic steroids) test system</td>
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<td>862.1390</td>
<td>5-Hydroxyindole acetic acid/serotonin test system</td>
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<td>862.1395</td>
<td>17-Hydroxy progesterone test system</td>
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<td>Hydroxyproline test system</td>
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<td>862.1405</td>
<td>Immunoassayable insulin test system</td>
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<td>862.1430</td>
<td>17-Ketosteroids test system</td>
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<tr>
<td>862.1435</td>
<td>Ketones (nonquantitative) test system</td>
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<td>Lactic acid test system</td>
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<td>Leucine aminopeptidase test system</td>
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<td>Lipase test system</td>
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<td>862.1475</td>
<td>Lipoprotein test system</td>
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<td>862.1485</td>
<td>Luteinizing hormone test system</td>
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<td>862.1500</td>
<td>Malic dehydrogenase test system</td>
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<td>862.1505</td>
<td>Mucopolysaccharides (nonquantitative) test system</td>
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<td>862.1510</td>
<td>Nitrile (nonquantitative) test system</td>
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<td>862.1520</td>
<td>5'-Nucleotidase test system</td>
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<td>862.1530</td>
<td>Plasma oncometry test system</td>
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<td>862.1535</td>
<td>Omithine carbamyltransferase test system</td>
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<td>862.2300</td>
<td>Colorimeter, photometer, or spectrophotometer for clinical use</td>
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<td>Densitometer/scanner (including reflectance, TLC, or radiochromatogram) for clinical use</td>
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<td>Enzyme analyzer for clinical use</td>
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<td>Blood mixing devices and blood weighing devices</td>
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<td>Cell-freezing apparatus and reagents for in vitro diagnostic use</td>
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<td>Blood bank centrifuge for in vitro diagnostic use</td>
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<td>Intraocular lens guide 19</td>
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<td>Sunglasses (nonprescription)</td>
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<td>Nuclear uptake probe</td>
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<td>Nuclear electrocardiograph synchronizer</td>
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<td>Radiographic ECG/respirator, synchronizer</td>
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<td>Manual radionucleide applicator system</td>
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<tr>
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</table>

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 864.7200.
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.
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.
PART 862-CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

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


2. Section 862.9 is revised to read as follows:

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

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

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

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

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

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

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

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

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;
(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

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

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

3. Section 862.1030 is amended by revising paragraph (b) to read as follows:

§ 862.1030 Alanine amino transferase (ALT/SGPT) test system.
* * * * *

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

4. Section 862.1040 is amended by revising paragraph (b) to read as follows:

§ 862.1040 Aldolase test system.
* * * * *

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

5. Section 862.1060 is amended by revising paragraph (b) to read as follows:

§ 862.1060 Delta-aminolevulinic acid test system.
* * * * *

(b) Classification. Class I (general controls). The device is exempt from 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.
(b) *Classification*. 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 **Etocholanolone test system.**
* * * *

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

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

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

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

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

§ 862.1325 **Gastrin test system.**
* * * *

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

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

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

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

§ 862.1335 Glucagon test system.

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

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

§ 862.1360 Gamma-glutamyl transpeptidase and isoenzymes test system.

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

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

§ 862.1370 Human growth hormone test system.

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

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

§ 862.1375 Histidine test system.

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

§ 862.1610 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.
(b) **Classification.** 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:

§ 862.1660  Quality control material (assayed and unassayed).

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

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:

\[\text{§ 862.1725 Trypsin test system.}\]

\* \* \* \* \* 

(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:

\[\text{§ 862.1780 Urinary calculi (stones) test system.}\]

\* \* \* \* \* 

(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:

\[\text{§ 862.1785 Urinary urobilinogen (nonquantitative) test system.}\]

\* \* \* \* \* 

(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:

\[\text{§ 862.1790 Uroporphyrin test system.}\]

\* \* \* \* \* 

(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 Microtitratar 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:


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


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.
(b) **Classification.** 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.**

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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.

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.

(b) Classification. 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.

(b) Classification. 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-1 -glycoproteins immunological test system.

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

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

§ 866.5425 Alpha-2-glycoproteins immunological test system.
(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

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

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

* * * * * *

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

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

§ 866.5440 Beta-2-glycoprotein 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 866.5715 is amended by revising paragraph (b) to read as follows:

§ 866.5715  Plasminogen immunological test system.

* * * * *

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

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

§ 866.5735  Prothrombin immunological test system.

* * * * *

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


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:
(b) **Classification.** 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:

§ 868.6610  **Tracheobronchial suction catheter.**

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

**PART 870-CARDIOVASCULAR DEVICES**

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


157. Section 870.9 is revised to read as follows:

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

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

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

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

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

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

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

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

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

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

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

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

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

PART 872—DENTAL DEVICES

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


159. Section 872.9 is revised to read as follows:
§ 872.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

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

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

(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.

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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.

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162. Section 872.3540 is amended by revising paragraph (b)(1) to read as follows:
§ 872.3540 OTC denture cushion or pad.

* * * * *

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

* * * * *

163. Section 872.6300 is revised to read as follows:

§ 872.6300 Rubber dam and accessories.

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

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

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

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

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

§ 872.6640 Dental operative unit and accessories.

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

PART 874-EAR, NOSE, AND THROAT DEVICES

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


167. Section 874.9 is revised to read as follows:

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

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

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for 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:

5874.1800  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:


181. Section 876.9 is revised to read as follows:

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

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

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

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

**\( \S \) 876.5250 Urine collector and accessories.**

(b) **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 \( \S \) 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:

**\( \S \) 876.5980 Gastrointestinal tube and accessories.**

(b) **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 \( \S \) 876.9.
186. The authority citation for 21 CFR part 878 continues to read as follows:


187. Section 878.9 is revised to read as follows:

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

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

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for 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.
(b) Classification. 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:


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:

(I) 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:


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 cannuia.

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

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

§ 882.4545 Shunt system implantation instrument.

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

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

§ 882.4650 Neurosurgical suture needle.

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

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

§ 882.4750 Skull punch.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 882.9. This exemption does not apply to powered compound cranial drills, burrs, trephines, and their accessories classified under § 882.4305.
PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

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


214. Section 884.9 is revised to read as follows:

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

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

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

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

(c) The device is an in vitro device that is intended:
(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

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

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

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

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

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

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

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

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

§ 884.1040 Viscometer for cervical mucus.

* * * * *

(b) Classification. 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

2 17. The authority citation for 21 CFR part 886 continues to read as follows:
84


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:


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:


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.
§ 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:


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.
(b) Classification. 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:


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

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

§ 892.2010 Medical image storage device.

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

244. Section 892.2020 is amended by revising paragraph (b) to read as follows:
§ 892.2020  Medical image communications device.

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

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

§ 892.5650  Manual radionuclide applicator system.

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

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

§ 892.6500  Personnel protective shield.

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

December 22, 1999

Linda S. Kahan
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