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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 864, 866, 868, ^{870,} 872, 874, 876, 878, 880, 882, 884, 886, ^{888,} 890, and 892

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R. P. [Signature]
11-6-98

[Docket No. 98N-0009]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend 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 proposing to designate 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 Food and Drug Administration Modernization Act of 1997 (FDAMA). FDA is taking this action in order to implement a requirement of FDAMA.

DATES: Written comments by (insert date 75 days after date of publication in the Federal Register).

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the act (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the 1976 amendments (Pub. L. 94-295), as amended by the SMDA (Pub. L. 101-629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to ensure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device, or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, part 807 (21 CFR part 807), require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether

the new device is substantially equivalent within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval. Unless exempted from premarket notification requirements, persons may not market a new device under section 510(k) of the act, unless they receive a substantial equivalence order from FDA or an order reclassifying the device into class I or class II, under section 513(f) of the act.

On November 21, 1997, the President signed FDAMA into law (Pub. L. 105–115). Section 206 of FDAMA, in part, added a new section 510(l) to the act. Under section 206 of the 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 these 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.

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. Responses to these comments are addressed in this document.

FDA is now proceeding 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). The devices FDA is proposing to designate as requiring premarket notification

include five devices that are currently exempt from premarket notification because FDA believes they meet the reserved criteria: *Quinine test system* § 862.3750 (21 CFR 862.3750), *Sulfonamide test system* § 862.3850 (21 CFR 862.3850), *Cardiopulmonary bypass accessory equipment* § 870.4200 (21 CFR 870.4200), *Ophthalmic eye shield* § 886.4750 (21 CFR 886.4750) (when made of other than plastic or aluminum), and *Electrode cable* § 890.1175 (21 CFR 890.1175). FDA also is proposing to modify the limitations language for all class I devices that are currently exempt.

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), for which a 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 that are intended for a use for which a misdiagnosis, as a result of using the device, could result in high morbidity or mortality, either 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.

Accordingly, because FDA believes that devices incorporating the characteristics described previously 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: (a) 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 (b) 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 (c) 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 and 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) to assess the risk of cardiovascular diseases; (5) for use in diabetes management; (6) to identify or infer the identity of a microorganism directly from clinical material; (7) 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; (8) 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 proposing to revise §§ 862.9, 864.9, and 866.9 (21 CFR 862.9, 864.9, and 866.9) to incorporate the revised limitations on exemptions for IVD's as set forth previously. FDA believes that these limitations, for the reasons described previously, are appropriate for IVD's.

FDA is also proposing to amend 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 proposed limitations language clarifies that these limitations apply to class II, as well as class I devices. On January 21, 1998 (63 FR 3142), FDA published a list of exempted class II devices, subject to certain limitations. Under section 510(m)(1), as added by FDAMA, FDA was provided the authority to exempt these class II devices upon issuance of a notice. FDA intends to codify these exemptions, including the limitations described in the January 21, 1998, **Federal Register** notice, by issuance of a final rule in the near future.

The limitations language that is proposed 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 proposed limitations sections state that the scope of these limitations apply to class II, as well as class I devices.

Second, FDA is proposing to amend 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 § _____.9 of each classification regulation part (e.g., §§ 862.9, 864.9, etc.) states 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;”.

FDA believes that devices that have an intended use that differs from any legally marketed device should not be 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 should 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 that FDA considers applicable to all class I devices that are described previously, FDA also considers certain devices within a generic class to 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 it considers liquid bandages generally to be exempt from the premarket notification requirements, but considers a subcategory of those devices, those intended for treatment of burns and other open wounds, to remain 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.

III. Analysis of Comments to the February 2, 1998, Notice

1. One comment proposed that general purpose instruments (21 CFR 862.2140, 862.2150, 862.2160, 862.2170, 862.2250, 862.2260, 862.2300, 862.2400, 862.2500, 862.2540, 862.2560, 862.2680, 862.2700, 862.2730, and 862.2750) designed to perform clinical testing that provide results that are intended to be of “substantial importance in preventing impairment of human health, or presents a potential risk of illness or injury” should not be exempt.

If these devices are not subject to the proposed limitations in § 862.9, FDA does not believe that premarket notification is necessary because these devices do not meet the reserved criteria. Laboratory instruments, like other devices, should be regulated according to risk and the risk associated with any device is related to intended use and indications for use. As general purpose instruments, these devices make no specific claims and their safety and effectiveness can be reasonably assured by using other general controls, including design controls (if the instrument

includes computer automation). If the labeling includes indications for specific analytes on the general purpose instrument, the devices would not meet the reserved criteria. Under proposed § 862.9, these devices would be subject to the limitations on exemptions and, therefore, would not be exempt from premarket notification. Review of the system and its indications by FDA would be required through a new premarket notification.

2. One comment stated that general purpose instruments should not be exempt from premarket notification because they could be used in a physician's office or near patient testing (point of care) by nonlaboratory trained individuals resulting in major threats to patient health.

FDA believes that these concerns are addressed by the limitations on exemptions. Under § 862.9(c), devices that are "for near patient testing (point of care)" would be excluded from exemption from premarket notification.

3. One comment stated that in vitro devices "intended for use in screening or diagnosis of familial and acquired genetic disorders including inborn errors of metabolism" (21 CFR 862.1330, 862.1335, 862.1560, 862.1595, and 862.1650) and test markers for endocrine disorders (21 CFR 862.1075, 862.1080, 862.1200, 862.1245, 862.1250, 862.1260, 862.1265, 862.1270, 862.1275, 862.1280, 862.1285, 862.1300, 862.1370, 862.1385, 862.1390, 862.1395, and 862.1620) should be subject to premarket notification.

FDA agrees that the manufacturer of the IVD's described by the comment may continue to be required to submit 510(k)'s under the proposed limitations on exemptions. Proposed limitations in § 862.9 would assure that these products will be subject to premarket notification requirements if intended for use in screening or diagnosis of familial or acquired genetic disorders or endocrine disorders and will not be subject to these requirements where the same device is not intended for these specific high risk indications. FDA, therefore, believes that these devices should be exempt from premarket notification, subject to the limitation.

4. One comment suggested that premarket notifications and review should be required for devices and tests designed to "identify or infer the identity of a microorganism directly from

clinical materials,” including devices classified under §§ 866.3145, 866.3375, 866.3405, 866.3480, 866.3500 and 866.3740.

FDA agrees. The comment has described one of the limitations on exemptions in the proposed rule. That limitation would apply to a number of classifications, including those cited by this comment.

5. One comment suggested that:

Quality control material—(assayed and unassayed) ([21 CFR] 862.1660), must continue to be reviewed so that the FDA oversight function may continue to identify those manufacturers of quality control reagents whose manufacturing or testing practices could fail to ensure a product of appropriate accuracy, stability, and reliability.

FDA agrees that quality control materials are of critical importance in laboratory operations. The agency intends to continue to review assayed quality control materials because it believes they meet the reserved criteria. FDA believes unassayed quality control materials, other than those used for donor screening, are appropriate for exemption from premarket review. Unlike unassayed quality control materials, assayed quality control materials have specifically labeled performance levels that are reviewed. The performance of unassayed quality control materials that are not labeled is not assessed in the 510(k) process and is assessed by the laboratory rather than the manufacturer. Issues such as stability and reliability for unassayed quality control materials are adequately addressed by the new quality systems requirements of current good manufacturing practices. Unassayed quality control materials for donor screening, however, should not be exempt because FDA should review the labeling to ensure no specific performance claims are made.

6. One comment indicated that there is an inconsistency between the exemptions of the free tyrosine test system (21 CFR 862.1730) and the galactose test system (21 CFR 862.1310), and the limitations on exemptions that apply to a device that “(c) is a in-vitro device that is intended: * * * (2) for use in screening or diagnosis of familial and acquired genetic disorders, including inborn errors of metabolism,” because all free tyrosine test systems and galactose test systems

are for those uses. Another comment stated that they were confused about the exemption from premarket notification of free tyrosine test systems and the limitations on exemptions, as noted previously.

FDA agrees there was an inconsistency. Because the devices are used for screening and diagnosis of genetic disorders and are related to significant morbidity and mortality associated with the disease entities identified by abnormalities in tyrosine and galactose metabolism, FDA believes these devices fit within the reserved criteria and should be added to the list of reserved class I devices that will continue to require premarket notification submissions.

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

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

8. One comment stated that FDA had previously exempted the unscented menstrual pad § 884.5435 (21 CFR 884.5435), from premarket notification, except for intralabial pads and reusable menstrual pads. The comment pointed out that the February 2, 1998, notice did not state whether these devices were reserved or exempted. The comment believes that FDA meant to exempt them and asked for clarification.

FDA has evaluated the use of intralabial pads and reusable menstrual pads and believes that they do meet the reserved criteria of FDAMA. These devices may present a potential unreasonable risk of illness or injury due to the risk of vaginal laceration, ulceration, vaginal microflora changes, and other possible adverse effects. FDA is, therefore, proposing to continue to designate the intralabial pads and reusable menstrual pads (§ 884.5435) as devices that require premarket notification.

9. One comment stated that FDA should exempt calipers because they do not meet the class I reserved criteria of FDAMA.

FDA concurs and notes that calipers were exempted on April 5, 1989 (54 FR 13826), under 21 CFR 878.4800 (manual surgical instrument for general use), subject to 21 CFR 878.9 limitations of exemptions from section 510(k) of the act.

10. Two comments expressed support for FDA's interpretation of section 510(l) of FDAMA and the agency's conclusion that devices identified in 21 CFR 874.3300(b)(1), air conduction hearing aids, meet the exemption criteria. One comment stated that "a device will lose its exemption if its intended use differs, or if it operates with a different fundamental scientific technology." The other comment added that the society he represented had concerns regarding FDA's "vigilance in insisting on adherence to FDA regulation governing the labeling and conditions for sale of hearing aids."

FDA agrees with the one comment on the scope of the limitations on exemptions. As far as FDA regulations governing the labeling, the agency believes that general controls are sufficient to regulate air-conduction hearing aids and that trade complaints will keep the agency well informed. The proposed regulation on conditions of sale of hearing aids is moving toward publication.

11. One comment responded to the February 2, 1998, notice by submitting a request for classification under section 513(g) of the act, requesting information regarding the requirements applicable to a dental water filter system with a treated filter/waterline under 21 CFR 872.6640.

FDA considers this comment a section 513(g) of the act request and will respond to the submitter in an individual response.

12. One comment requested that the 510(k) the comment submitted for a class I device classified under § 884.1040 (21 CFR 884.1040) *Viscometer for cervical mucus*, be found to be exempt from the section 510(k) requirements of the act. The comment stated that "the device is not intended for a use which is of substantial importance in preventing impairment of human

health and does not present a potential unreasonable risk of illness or injury (“reserved criteria”)) and should not be placed under the reserved criteria found in section 206 of FDAMA.

FDA agrees that, generally, viscometers for cervical mucus (§ 884.1040) do not meet the “reserved” criteria under FDAMA and did place this classification regulation on the list of exempted devices in the February 2, 1998, notice. Consistent with the February 2, 1998, notice, FDA is proposing to designate viscometers for cervical use exempt from 510(k) requirements. The comment’s device, however, would use a new matrix for this device. FDA believes that this represents a different intended use that would make this device subject to the limitations on exemptions and, therefore, ineligible for exemption.

13. One comment questioned the limitations on exemptions stated in the February 2, 1998, notice, particularly the limitations applicable to IVD’s that are noninvasive tests. The comment criticized the use of the words “noninvasive testing” as being overly broad.

FDA disagrees with this comment. FDA believes that the limitations are necessary to assure that devices are not marketed that are significantly different from the devices exempted from premarket notification, particularly in the area of IVD’s where devices are often subject to changes in intended use and conditions of use. Noninvasive testing devices should not be exempt because they almost always involve novel matrices and novel technologies. However, FDA is clarifying the phrase, “noninvasive testing,” by citing the definition of “noninvasive” found in § 812.3(k) in the proposed limitations on exemptions.

14. One comment suggested that FDA should review the exemptions and reservations in existing classifications to assure that the present lists are consistent with those listed in the February 2, 1998, notice.

FDA has reviewed the existing regulations again and is proposing to reserve five currently exempted device classifications (§§ 862.3750, 862.3850, 870.4200, 886.4750, and 890.1175).

15. One comment suggested that FDA reserve 11 class I devices that FDA stated it considered exempt class I devices in the February 2, 1998, **Federal Register** notice and subject them to section

510(k) of the act requirements, including: *Cultured animal and human cells* (21 CFR 864.2280); *Microorganism differentiation and identification device* (21 CFR 866.2660); *Coxsackievirus serological reagents* (21 CFR 866.3145); *Echinococcus spp. serological reagents* (21 CFR 866.3200); *Equine encephalomyelitis virus serological reagents* (21 CFR 866.3240); *Lymphocytic choriomeningitis virus serological reagents* (21 CFR 866.3360); *Mumps virus serological reagents* (21 CFR 866.3380); *Poliovirus serological reagents* (21 CFR 866.3405); *Trichinella spiralis serological reagents* (21 CFR 866.3850); *Rickettsia serological reagents* (21 CFR 866.3500); and *Streptococcus spp. serological reagents* (21 CFR 866.3740).

FDA does not agree with the comment that these devices meet the reserved criteria. FDA notes the limitations on exemptions are specifically designed to maintain premarket review for devices used in “screening, diagnosis, or monitoring life threatening diseases” or “to infer the identity of a microorganism directly from clinical material.” While section 510(k) of the act exemptions would apply to devices marketed for uses the agency would consider lower risk, such as determination of immune status or for epidemiological uses of these devices, they would not apply to devices with diagnostic claims for use in life-threatening disease states or for direct detection of a microorganism using clinical material. Therefore, FDA is proposing to designate these 11 devices as exempt from section 510(k) of the act requirements subject to the limitations on exemptions.

16. One comment suggested that the limitations on exemptions are unnecessary, confusing, and difficult to apply, especially to IVD’s. This comment additionally notes “we question the basis for FDA’s broad restrictions in such a specific category of devices.”

FDA does not agree that the language is unnecessary, confusing, or difficult to apply. The limitations language that was in the February 2, 1998, **Federal Register** notice, and that is proposed for all class I devices modifies the limitations on exemptions currently found in § _____.9 of each device classification regulation part (e.g., §§ 862.9, 864.9, etc.) only in three ways. First, FDA has referenced class II devices to reflect that both class I and class II devices may be exempted

in accordance with new section 510(l) and (m). Second, the limitations language modifies current limitations language by stating that devices are to be compared to “any legally marketed device in that generic type of device” rather than a device on the market “before May 28, 1976” or a “preamendments device to which it has been determined substantially equivalent.” Third, the limitations language adds specific language relating to IVD’s. The agency cannot predict all possible different intended uses or changes in fundamental scientific technologies that may significantly affect safety and effectiveness; limitations on exemptions are, therefore, in the best interest of the public health because they ensure that devices incorporating such changes will be reviewed for safety and effectiveness by the agency before they go to market.

In order to efficiently allocate review resources, the agency has developed a risk-based approach toward use of the limitations on exemptions to ensure that high-risk devices remain subject to premarket review. The limitations on exemptions continue to take into account two critical risk elements—intended use and novelty of technology.

Furthermore, FDA believes that in vitro diagnostic devices are unique because their safety and effectiveness relates primarily to the information generated by these devices rather than the direct interaction between device and patient. FDA has more fully discussed the need for these limitations earlier in this document.

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

With regard to the first limitation (“has an intended use that is different from the intended use of a legally marketed device in that generic type”), we believe that current law is clear that if a device has an intended use different than that expressed in the definition contained in the Code of Federal Regulations (CFR), such device would not be the same as the exempted device. The exemption would simply not apply to that device. However, “intended use” can encompass many different concepts that go beyond the general intended use statements that comprised the CFR definitions. There has been some controversy, for instance, over the extent to which indications for use can change intended use. Our position is that any indication for use that has been included in a previous 510(k) order of classification identifies

the scope of the intended use for each exempt type of device. Minor variances of indications for use within the intended use of an exempt type of device should have no effect on the status of a 510(k) exemption.

FDA has interpreted § _____.9(a) in the limitations on exemptions under the current regulations to mean that any legally marketed device (as defined in 21 CFR 807.92(a)(3)) within a device classification regulation may serve as a predicate for another manufacturer's device and the other manufacturer's device may be exempt. FDA believes that any additional indication for use for an exempt classification device type (i.e., an indication not previously cleared) is considered a different intended use and does not meet the limitations on exemptions, and therefore, requires a new premarket notification. FDA agrees that minor variances in indications would not affect the exemption status of the classification. FDA notes that in its guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device," FDA states, in regard to minor variances in indications of closely related populations, "If the expansion is to a population with similar demographics, diagnosis, prognosis, comorbidity and potential for complications as the original, then a new 510(k) is not ordinarily expected."

18. On its own initiative, FDA is proposing to require premarket notification for five devices that are currently exempt from premarket notification: Quinine test system (§ 862.3750), sulfonamide test system (§ 862.3850), cardiopulmonary bypass accessory equipment (§ 870.4200), electrode cable (§ 890.1175), and ophthalmic eye shield (when made of other than plastic or aluminum) (§ 886.4750).

IV. FDA Proposal to Revoke Exemptions

A. Quinine Test System (§ 862.3750) and Sulfonamide Test System (§ 862.3850)

On June 8, 1988 (53 FR 21447), FDA published a final rule exempting the quinine test system and the sulfonamide test system from premarket notification requirements. FDA stated that it was

exempting these products because it believed that premarket notification was not necessary to protect the public health.

The quinine test system is used to measure quinine, a fever-reducing and pain-relieving drug used to treat malaria, in the serum or urine. Measurements obtained by this device are used in the diagnosis and treatment of quinine overdose and malaria. If this device fails, persons who have malaria may suffer serious life-threatening consequences by not receiving the appropriate amount of quinine. Similarly, the sulfonamide test system is intended to measure sulfonamide levels which are used to treat life-threatening bacterial infections. The failure of this device may also result in the improper treatment of a life-threatening disease.

Given that these devices are used in determining the treatments for life-threatening diseases, and an inaccurate measurement of the treatment drug could result in life-threatening consequences, FDA does not believe that its previous determinations to exempt these devices from premarket notification were correct. Accordingly, FDA believes that premarket review is necessary to assure the safety and effectiveness of these devices. Moreover, FDA believes that these products meet the reserved criteria for premarket review under section 510(I), in that they are intended for a use which is of substantial importance in preventing impairment of human health, and present a potential unreasonable risk of illness or injury. Therefore, FDA is proposing to require manufacturers of these products to submit premarket notifications.

B. Ophthalmic Eye Shields (§ 886.4750)

On September 2, 1987 (52 FR 33366), FDA published a final rule classifying ophthalmic eye shields as class I devices. This generic type of device is described in § 886.4750 as “a device that consists of a plastic or aluminum eye covering intended to protect the eye or retain dressing materials in place.” Plastic or aluminum eye shields rest over the forehead and cheek and do not contact the eye.

Since that classification, FDA has found eye shields that are made of collagen substantially equivalent to eye shields made out of plastic or aluminum in § 886.4750. Collagen eye shields,

unlike aluminum and plastic eye shields, come in direct contact with the cornea and are indicated for relief of discomfort from post-surgical, traumatic and nontraumatic corneal conditions. Unlike aluminum and plastic eye shields, there are toxicological concerns relating to biocompatibility and dissolving time for collagen materials. In premarket reviews, FDA has examined biocompatibility and dissolving issues in determining the substantial equivalence of collagen eye shields to plastic and aluminum eye shields.

On December 7, 1994 (59 FR 63005), FDA published a final rule exempting this classification from premarket notification requirements, and quality systems requirements, except 21 CFR 820.198, with respect to complaint files. FDA erred in not amending the codified language at that time to retain premarket review and quality system requirements for collagen eye shields that had been placed in that classification. Despite the exemption language, FDA has continued to receive and review premarket notifications for eye shields made out of collagen.

Because the toxicological issues cause the product to meet the reserved criteria in that the devices are intended for a use which is of substantial importance in preventing impairment of human health or present a potential unreasonable risk of illness or injury, FDA is proposing to amend the codified text to state that collagen eye shields are not exempt from premarket notification requirements.

C. Cardiopulmonary Bypass Accessory Equipment (§ 870.4200) and Electrode Cable (§ 890.1175)

On June 12, 1989 (54 FR 25042), FDA published a final rule exempting electrode cables (§ 890.1175) and cardiopulmonary bypass accessory equipment (§ 870.4200) from premarket notification requirements. FDA received numerous reports of deaths and injuries associated with unprotected patient cables and lead wires. To address the risk of patient exposure to macro shock or electrocution due to the inappropriate connection of a patient connected cable or electrode lead wire to an alternating current power source, in the **Federal Register** of May 9, 1997 (62 FR 25477), FDA published a final rule establishing a performance standard for cables and leads. In the preamble of that final rule, FDA announced that it intended to reclassify electrode cables

(§ 890.1175) and cardiopulmonary bypass accessory equipment (§ 870.4200) to class II to subject them to this performance standard. In the meantime, FDA is proposing to subject these devices to premarket review to assure that they are safe and effective, pending the rulemaking to reclassify them into class II.

V. Proposed Designation of Devices

In the **Federal Register** of February 2, 1998 (63 FR 5387), FDA issued a notice of its intent to propose to exempt a list of class I (general controls) devices from the requirement of premarket notification, subject to the limitations of exemptions. FDA has reviewed that list and other devices in light of the comments received in response to the February 2, 1998, notice and other information that has come to FDA's attention. As a result, FDA is proposing to designate as exempt certain devices that were not listed as exempt in the February 2, 1998, notice and to designate as reserved devices certain devices that were not designated as reserved in the February 2, 1998, notice or that were previously exempted by regulation.

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

TABLE 1.—PROPOSED DESIGNATIONS OF RESERVED CLASS I DEVICES

21 CFR Section	Name of Device
862.1065	Ammonia test system
862.1113	Bilirubin (total and unbound) in the neonate test system
862.1310	Galactose test system
862.1410	Iron (non-heme) test system
862.1415	Iron-binding capacity test system
862.1495	Magnesium test system
862.1580	Phosphorous (inorganic) test system
862.1660	Quality control material (assayed and unassayed) ¹
862.1680	Testosterone test system
862.1730	Free tyrosine test system
862.1775	Uric acid test system
862.3050	Breath-alcohol test system
862.3110	Antimony test system
862.3120	Arsenic test system
862.3220	Carbon monoxide test system
862.3240	Cholinesterase test system
862.3280	Clinical toxicology control material (assayed and unassayed) ¹
862.3600	Mercury test system
862.3750	Quinine test system
862.3850	Sulfonamide test system
864.7040	Adenosine triphosphate release assay
864.8950	Russell viper venom reagent
864.9050	Blood bank supplies
864.9125	Vacuum-assisted blood collection system ²

TABLE 1.—PROPOSED DESIGNATIONS OF RESERVED CLASS I DEVICES—Continued

21 CFR Section	Name of Device
864.9195	Blood mixing devices and blood weighing devices ²
866.2390	Transport culture medium
866.2560	Microbial growth monitor ³
866.2850	Automated zone reader
866.2900	Microbiological specimen collection and transport device
866.3110	Campylobacter fetus serological reagents
866.3120	Chlamydia serological reagents
866.3235	Epstein-Barr virus serological reagents
866.3370	Mycobacterium tuberculosis immunofluorescent reagents
866.3870	Trypanosoma spp. serological reagents
870.4200	Cardiopulmonary bypass accessory equipment
872.3700	Dental mercury
872.4200	Dental handpiece and accessories
872.6250	Dental chair and accessories ⁴
872.6640	Dental operative unit and accessories ⁵
872.6710	Boiling water sterilizer
876.5160	Urological clamps for males ⁶
878.4460	Surgeon's glove
880.5090	Liquid bandage ⁷
880.5680	Pediatric position holder
880.6250	Patient examination glove
880.6375	Patient lubricant
880.6760	Protective restraint
882.1030	Ataxiagraph
882.1420	Electroencephalogram (EEG) signal spectrum analyzer
882.4060	Ventricular cannula ⁸
882.4545	Shunt system implantation instrument ⁹
884.2980(a)	Telethermographic system ¹⁰
884.2982(a)	Liquid crystal thermographic system ¹¹
884.5435	Unscented menstrual pads (intra-labial pads and reusable menstrual pads)
886.4070	Powered corneal burr ¹²
886.4300	Intraocular lens guide ¹³
886.4370	Keratome
886.4750	Ophthalmic eye shield (when made of other than plastic or aluminum)
888.1500	Goniometer
890.1175	Electrode cable
890.3850	Mechanical wheelchair
890.5710	Hot or cold disposable pack ¹⁴
892.1100	Scintillation (gamma) camera
892.1110	Positron camera

¹ Meets reserved criteria for all assayed and only the unassayed when used for donor screening.

² Meets reserved criteria when automated.

³ Meets reserved criteria when automated blood culturing systems.

⁴ Meets reserved criteria when dental chair with the operative unit.

⁵ Meets reserved criteria when it is not an accessory to the unit.

⁶ Meets reserved criteria when devices are for internal use or are used for females.

⁷ Meets reserved criteria for uses other than as a skin protectant.

⁸ Meets reserved criteria if not made of surgical grade stainless steel.

⁹ Meets reserved criteria if not made of surgical stainless steel.

¹⁰ Meets reserved criteria if an adjunct use system.

¹¹ Meets reserved criteria if nonelectrically powered and AC-powered adjunctive system.

¹² Meets reserved criteria if for use other than for removing rust rings.

¹³ Meets reserved criteria if used as folders and injectors for soft or foldable intraocular lenses (IOL's).

¹⁴ Meets reserved criteria if indicated for use on infants.

FDA is proposing to amend the regulations to designate the following devices as exempt from premarket notification because FDA believes that they do not meet the reserved criteria under section 206 of the FDAMA that adds new section 510(I) of the act:

TABLE 2.—PROPOSED DESIGNATIONS OF EXEMPTED CLASS I DEVICES

21 CFR Section	Name of Device
862.1030	Alanine amino transferase (ALT/SGPT) test system
862.1040	Aldolase test system
862.1060	Delta-aminolevulinic acid test system
862.1075	Androstenedione test system

TABLE 2.—PROPOSED DESIGNATIONS OF EXEMPTED CLASS I DEVICES—Continued

21 CFR Section	Name of Device
862.1080	Androsterone test system
862.1095	Ascorbic acid test system
862.1115	Urinary bilirubin and its conjugates (nonquantitative) test system
862.1130	Blood volume test system
862.1135	C-peptides of proinsulin test system
862.1165	Catecholamines (total) test system
862.1175	Cholesterol (total) test
862.1180	Chymotrypsin test system
862.1185	Compound S (11-deoxycortisol) test system
862.1195	Corticoids test system
862.1200	Corticosterone test system
862.1240	Cystine test system
862.1245	Dehydroepiandrosterone (free and sulfate) test system
862.1250	Desoxycorticosterone test system
862.1260	Estradiol test system
862.1265	Estriol test system
862.1270	Estrogens (total, in pregnancy) test system
862.1275	Estrogens (total, nonpregnancy) test system
862.1280	Estrone test system
862.1285	Etiocholanolone test system
862.1300	Follicle-stimulating hormone test system
862.1325	Gastrin test system
862.1330	Globulin test system
862.1335	Glucagon test system
862.1360	Gamma-glutamyl transpeptidase and isoenzymes test system
862.1370	Human growth hormone test system
862.1375	Histidine test system
862.1385	17-Hydroxycorticosteroids (17-ketogenic steroids) test system
862.1390	5-Hydroxyindole acetic acid/serotonin test system
862.1395	17-Hydroxyprogesterone test system
862.1400	Hydroxyproline test system
862.1405	Immunoreactive insulin test system
862.1430	17-Ketosteroids test system
862.1435	Ketones (nonquantitative) test system
862.1450	Lactic acid test system
862.1460	Leucine aminopeptidase test system
862.1465	Lipase test system
862.1475	Lipoprotein test system
862.1485	Luteinizing hormone test system
862.1500	Malic dehydrogenase test system
862.1505	Mucopolysaccharides (nonquantitative) test system
862.1510	Nitrite (nonquantitative) test system
862.1520	5'-Nucleotidase test system
862.1530	Plasma oncometry test system
862.1535	Ornithine carbamyl transferase test system
862.1540	Osmolality test system
862.1542	Oxalate test system
862.1550	Urinary pH (nonquantitative) test system
862.1560	Urinary phenylketones (nonquantitative) test system
862.1570	Phosphohexose isomerase test system
862.1590	Porphobilinogen test system
862.1595	Porphyrins test system
862.1605	Pregnanediol test system
862.1610	Pregnanetriol test system
862.1615	Pregnenolone test system
862.1620	Progesterone test system
862.1625	Prolactin (lactogen) test system
862.1630	Protein (fractionation) test system
862.1645	Urinary protein or albumin (nonquantitative) test system
862.1650	Pyruvate kinase test system
862.1655	Pyruvic acid test system
862.1660	Quality control material (assayed and unassayed) ¹
862.1705	Triglyceride test system
862.1725	Trypsin test system
862.1780	Urinary calculi (stones) test system
862.1785	Urinary urobilinogen (nonquantitative) test system
862.1790	Uroporphyrin test system
862.1795	Vanilmandelic acid test system
862.1805	Vitamin A test system
862.1820	Xylose test system
862.2140	Centrifugal chemistry analyzer for clinical use
862.2150	Continuous flow sequential multiple chemistry analyzer for clinical use

TABLE 2.—PROPOSED DESIGNATIONS OF EXEMPTED CLASS I DEVICES—Continued

21 CFR Section	Name of Device
862.2160	Discrete photometric chemistry analyzer for clinical use
862.2170	Micro chemistry analyzer for clinical use
862.2250	Gas liquid chromatography system for clinical use
862.2260	High pressure liquid chromatography system for clinical use
862.2270	Thin-layer chromatography system for clinical use
862.2300	Colorimeter, photometer, or spectrophotometer for clinical use
862.2400	Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use
862.2500	Enzyme analyzer for clinical use
862.2540	Flame emission photometer for clinical use
862.2560	Fluorometer for clinical use
862.2680	Microtitrator for clinical use
862.2700	Nephelometer for clinical use
862.2730	Osmometer for clinical use
862.2750	Pipetting and diluting system for clinical use
862.2850	Atomic absorption spectrophotometer for clinical use
862.2860	Mass spectrometer for clinical
862.2900	Automated urinalysis system
862.3280	Clinical toxicology control material (assayed and unassayed) ¹
864.2280	Cultured animal and human cells
864.3250	Specimen transport and storage container
864.5240	Automated blood cell diluting apparatus
864.6150	Capillary blood collection tube
864.9125	Vacuum-assisted blood collection system ²
864.9185	Blood grouping view box
864.9195	Blood mixing devices and blood weighing devices ²
864.9225	Cell-freezing apparatus and reagents for in vitro diagnostic use
864.9275	Blood bank centrifuge for in vitro diagnostic use
864.9320	Copper sulphate solution for specific gravity determinations
864.9750	Heat-sealing device
866.2660	Microorganism differentiation and identification device
866.3040	Aspergillus spp. serological reagents
866.3140	Corynebacterium spp. serological reagents
866.3145	Coxsackievirus serological reagents
866.3200	Echinococcus spp. serological reagents
866.3240	Equine encephalomyelitis virus serological reagents
866.3355	Listeria spp. serological reagents
866.3360	Lymphocytic choriomeningitis virus serological reagents
866.3375	Mycoplasma spp. serological reagents
866.3380	Mumps virus serological reagents
866.3405	Poliovirus serological reagents
866.3480	Respiratory syncytial virus serological reagents
866.3500	Rickettsia serological reagents
866.3600	Schistosoma spp. serological reagents
866.3680	Sporothrix schenckii serological reagents
866.3740	Streptococcus spp. serological reagents
866.3850	Trichinella spiralis serological reagents
866.5060	Prealbumin immunological test system
866.5065	Human allotypic marker immunological test system
866.5160	Beta-globulin immunological test system
866.5200	Carbonic anhydrase B and C immunological test
866.5330	Factor XIII, A, S, immunological test system ³
866.5400	Alpha-globulin immunological test system
866.5420	Alpha-1-glycoproteins immunological test system
866.5425	Alpha-2-glycoproteins immunological test system
866.5430	Beta-2-glycoprotein I immunological test system
866.5440	Beta-2-glycoprotein III immunological test system
866.5560	Lactic dehydrogenase immunological test system
866.5570	Lactoferrin immunological test system
866.5590	Lipoprotein X immunological test system
866.5715	Plasminogen immunological test system
866.5735	Prothrombin immunological test system ⁴
866.5765	Retinol-binding protein immunological test system
866.5890	Inter-alpha trypsin inhibitor immunological test system
868.1910	Esophageal stethoscope
868.5620	Breathing mouthpiece
868.5640	Medicinal nonventilatory nebulizer (atomizer)
868.5675	Rebreathing device
868.5700	Nonpowered oxygen tent
868.6810	Tracheobronchial suction catheter
872.3275(a)(1)	Dental cement (zinc oxide-eugenol)
872.3400(b)(1)	Karaya and sodium borate with or without acacia denture adhesive (less than 12 percent sodium borate by weight)

TABLE 2.—PROPOSED DESIGNATIONS OF EXEMPTED CLASS I DEVICES—Continued

21 CFR Section	Name of Device
872.3540(b)(1)	OTC denture cushion or pad ⁵
872.6300	Rubber dam ⁶
872.6390	Dental floss
874.1070	Short increment sensitivity index (SISI) adapter
874.1100	Earphone cushion for audiometric testing
874.1500	Gustometer
874.1800	Air or water caloric stimulator
874.1925	Toynbee diagnostic tube
874.3300(b)(1)	Hearing aid ⁶
874.3540	Prosthesis modification instrument for ossicular replacement surgery
874.4100	Epistaxis balloon
874.4420	Ear, nose, and throat manual surgical instrument
874.5300	Ear, nose, and throat examination and treatment unit
874.5550	Powered nasal irrigator
874.5840	Antistammering device
876.5160	Urological clamp for males ⁷
876.5210	Enema kit
876.5250(b)(2)	Urine collector and accessories ⁸
876.5980(b)(2)	Gastrointestinal tube and accessories ⁹
878.3250	External facial fracture fixation appliance
878.3910	Noninflatable extremity splint
878.3925	Plastic surgery kit and accessories
878.4040	Surgical apparel ¹⁰
878.4100	Organ bag
878.4200	Introduction/drainage catheter and accessories
878.4320	Removable skin clip
878.4680	Nonpowered, single patient, portable suction apparatus
878.4760	Removable skin staple
878.4820	Surgical instrument motors and accessories/attachments
878.4960	Operating tables and accessories and operating chairs and accessories
880.5090	Liquid bandage ¹¹
880.5270	Neonatal eye pad
880.5420	Pressure infusor for an I.V. bag
882.1200	Two-point discriminator
882.1500	Esthesiometer
882.1750	Pinwheel
882.4060	Ventricular cannula ¹²
882.4545	Shunt system implantation instrument ¹³
882.4650	Neurosurgical suture needle
882.4750	Skull punch ¹⁴
884.1040	Viscometer for cervical mucus
886.1780	Retinoscope ¹⁵
886.1940	Tonometer sterilizer
886.4070	Powered corneal burr ¹⁶
886.4300	Intraocular lens guide ¹⁷
886.5850	Sunglasses (nonprescription)
890.5180	Manual patient rotation bed
890.5710	Hot or cold disposable pack ¹⁸
892.1300	Nuclear rectilinear scanner
892.1320	Nuclear uptake probe
892.1330	Nuclear whole body scanner
892.1350	Nuclear scanning bed
892.1410	Nuclear electrocardiograph synchronizer
892.1890	Radiographic film illuminator
892.1910	Radiographic grid
892.1960	Radiographic intensifying screen
892.1970	Radiographic ECG/respirator, synchronizer
892.2010	Medical image storage device
892.2020	Medical image communication device
892.5650	Manual radionuclide applicator system
892.6500	Personnel protective shield

¹ Exemption is limited to unassayed material, except when used in conjunction with donor screening tests.

² Exemption is limited to manual devices.

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

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

⁵ This exemption does not apply to class III OTC denture cushion as described in 21 CFR 872.3540(b)(2).

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

⁷ Exemption is limited to air-conduction hearing aids.

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

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

- ¹⁰ Exemption is limited to dissolvable nasogastric feed tube guide for the nasogastric tube in § 876.5980(b)(2) (21 CFR 876.5980(b)(2)). Exemption does not include class II devices as described in § 876.5980(b)(1).
- ¹¹ Exemption is limited to class I category other than surgical gowns and surgical masks.
- ¹² Exemption is limited to uses as a skin protectant.
- ¹³ Exemption is limited to devices made of surgical grade stainless steel.
- ¹⁴ Exemption is limited to devices made of surgical grade stainless steel.
- ¹⁵ Exemption should not be confused with 21 CFR 882.4305.
- ¹⁶ Exemption is limited to class I battery-powered devices.
- ¹⁷ Exemption is limited to rust ring removal.
- ¹⁸ Exemption does not apply if used as folders and injectors for soft or foldable IOL's.
- ¹⁹ Exemption does not apply when indicated for infants.

Deleted in Table during revision. added to delete fl. note

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VI. Differences Between the February 2, 1998, List of Exempt and Reserved Devices, and List of Exempt and Reserved Devices Proposed Herein

As stated previously, FDA issued a notice on February 2, 1998, in the **Federal Register** that listed the devices that it considered exempt from 510(k) requirements (exempt), and those it considered subject to 510(k) requirements (reserved) under new section 510(l). This document proposes to designate the reserved and exempt lists by notice and comment rulemaking. Although most of the device categories listed in the February 2, 1998, notice, and the device categories listed in this proposal are identical, there are a few differences. These differences are described in the following lists:

TABLE 3.—PROPOSED RESERVED DEVICES THAT ARE CURRENTLY EXEMPTED BY REGULATION

21 CFR Section	Name of Device
862.3750	Quinine test system
862.3850	Sulfonamide test system
870.4200	Cardiopulmonary bypass accessory equipment
886.4750	Ophthalmic eye shield (when made of other than plastic or aluminum)
890.1175	Electrode cable

TABLE 4.—ADDITIONAL PROPOSED RESERVED DEVICES NOT CONSIDERED RESERVED UNDER THE FEBRUARY 2, 1998, FEDERAL REGISTER NOTICE

21 CFR Section	Name of Device
862.3050	Breath alcohol test system
872.3700	Dental Mercury
884.5435	Unscented menstrual pads (intralabial pads and reusable menstrual pads)

TABLE 5.—ADDITIONAL PROPOSED EXEMPTED DEVICES NOT CONSIDERED EXEMPTED IN THE FEBRUARY 2, 1998, FEDERAL REGISTER NOTICE

21 CFR Section	Name of Device
864.3250	Specimen transport and storage container (OTC)
864.6150	Capillary blood collection tube
872.3275(a)(1)	Dental cement (zinc oxide-eugenol)
872.3540(b)(1)	OTC dental cushion or pad (wax impregnated cotton cloth)
872.6300	Rubber dam
874.1100	Earphone cushion for audiometric testing
874.3540	Prosthesis modification instrument for ossicular replacement surgery
874.4420	Ear, nose, and throat manual surgical instrument
876.5980(b)(2)	Gastrointestinal tube and accessories (dissolvable nasogastric feed tube guide for the nasogastric tube)
878.3250	External facial fracture appliance

TABLE 5.—ADDITIONAL PROPOSED EXEMPTED DEVICES NOT CONSIDERED EXEMPTED IN THE FEBRUARY 2, 1998, FEDERAL REGISTER NOTICE—Continued

21 CFR Section	Name of Device
878.3910	Noninflatable extremity splint
878.3925	Plastic surgery kit and accessories
878.4100	Organ bag
882.1200	Two point discriminator
882.1500	Esthesiometer
882.1750	Pinwheel
892.1350	Nuclear scanning bed
892.2010	Medical image storage device
892.2020	Medical image communication device
892.6500	Personnel protective shield

VII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that these proposed 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.

VIII. Analysis of Impacts

FDA has examined the impacts of the proposed 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 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages distributive impacts and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed 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 proposed rule would reduce a regulatory

burden by exempting manufacturers of devices subject to the rule from the requirements of premarket notification.

FDA is proposing to require premarket notification for 5 devices that were previously exempt from premarket notification. These devices are as follows:

A. Cardiopulmonary Bypass Accessory Equipment (§ 870.4200) and Electrode Cable (§ 890.1175).

In the **Federal Register** of May 9, 1997 (62 FR 25477), FDA published a final rule to establish a performance standard for electrode lead wires and patient cables. In the preamble to that rule (62 FR 25485), FDA noted that three unprotected cable and electrode lead wire systems are included in class I devices, and, as such, are not subject to a mandatory performance standard. These include the two devices listed previously and the AC-powered goniometer (21 CFR 888.1500). FDA further stated that, because of the degree of health risk, the agency intended to reclassify the devices into class II so that they would be subject to the mandatory performance standard. The cardiopulmonary bypass accessory equipment and the electrode cable were already exempt from premarket notification; the AC-powered goniometer was not. Because of the degree of health risk, FDA believes that these devices should be designated as reserved devices.

FDA also included in the preamble of the May 9, 1997, rule an assessment of the economic impact of imposition of the standard including an assessment of its effect on small businesses. In this assessment, FDA included the three class I devices to which the rule would later apply. FDA concluded that the rule would not have a significant economic impact on a substantial number of small entities. This rule would only impose the additional requirement of submitting a premarket notification for these devices. Because the premarket notification would consist primarily of a certification of compliance with the cables and leads standard, FDA believes that this requirement will not be a significant burden.

B. 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. FDA would be primarily interested in the biocompatibility of the devices. FDA estimates that preparation of such a premarket notification would cost no more than \$5,000.

C. 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 1 year.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed 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.

X. Comments

Interested persons may, on or before (*insert date 75 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Parts 862, 868, ^{§ 709} 872, 874, 876, 878, 880, 882, 884, ^{§ 888} and 890

Medical devices.

21 CFR Part 864

Blood, Medical devices, Packaging and containers.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA is proposing to amend 21 CFR parts 862, 864, 866, 868, ^{§ 709} 872, 874, 876, 878, 880, 882, 884, 886, ^{§ 888} 890, and 892 as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

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

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

2. Section 862.9 is revised to read as follows:

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

The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or

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II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

(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:

§ 862.1115 Urinary bilirubin and its conjugates (nonquantitative) test system.

* * * * *

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

10. Section 862.1130 is amended by revising paragraph (b) to read as follows:

§ 862.1130 Blood volume test system.

* * * * *

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

11. Section 862.1135 is amended by revising paragraph (b) to read as follows:

§ 862.1135 C-peptides of proinsulin test system.

* * * * *

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

12. Section 862.1165 is amended by revising paragraph (b) to read 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 (11-deoxycortisol) test system.

* * * * *

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

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

§ 862.1195 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:

§ 862.1260 Estradiol test system.

* * * * *

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

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

§ 862.1265 Estriol test system.

* * * * *

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

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

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

* * * * *

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

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

§ 862.1275 Estrogens (total, nonpregnancy) test system.

* * * * *

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

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

§ 862.1280 Estrone test system.

* * * * *

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

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

§ 862.1285 Etiocholanolone test system.

* * * * *

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

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

§ 862.1300 Follicle-stimulating hormone test system.

* * * * *

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

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

§ 862.1325 Gastrin test system.

* * * * *

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

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

§ 862.1330 Globulin test system.

* * * * *

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

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

§ 862.1335 Glucagon test system.

* * * * *

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

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

§ 862.1360 Gamma-glutamyl transpeptidase and isoenzymes test system.

* * * * *

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

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

§ 862.1370 Human growth hormone test system.

* * * * *

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

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

§ 862.1375 Histidine test system.

* * * * *

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

34. Section 862.1385 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:

§ 862.1560 Urinary phenylketones (nonquantitative) test system.

* * * * *

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

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.

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

§ 862.1615 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:

§ 862.1725 Trypsin test system.

* * * * *

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

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

§ 862.1780 Urinary calculi (stones) test system.

* * * * *

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

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

§ 862.1785 Urinary urobilinogen (nonquantitative) test system.

* * * * *

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

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

§ 862.1790 Uroporphyrin test system.

* * * * *

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

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

§ 862.1795 Vanilmandelic acid test system.

* * * * *

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

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

§ 862.1805 Vitamin A test system.

* * * * *

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

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

§ 862.1820 Xylose test system.

* * * * *

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

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

§ 862.2140 Centrifugal chemistry analyzer for clinical use.

* * * * *

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

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

§ 862.2150 Continuous flow sequential multiple chemistry analyzer for clinical use.

* * * * *

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

79. Section 862.2160 is amended by revising paragraph (b) to read as follows:

§ 862.2160 Discrete photometric chemistry analyzer for clinical use.

* * * * *

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

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

§ 862.2170 Micro chemistry analyzer for clinical use.

* * * * *

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

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

§ 862.2250 Gas liquid chromatography system for clinical use.

* * * * *

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

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

§ 862.2260 High pressure liquid chromatography system for clinical use.

* * * * *

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

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

§ 862.2270 Thin-layer chromatography system for clinical use.

* * * * *

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

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

of this chapter

§ 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:

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§ 862.2400 Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use.

* * * * *

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

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

§ 862.2500 Enzyme analyzer for clinical use.

* * * * *

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

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

§ 862.2540 Flame emission photometer for clinical use.

* * * * *

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

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

§ 862.2560 Fluorometer for clinical use.

* * * * *

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

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

§ 862.2680 Microtitrator for clinical use.

* * * * *

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

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

§ 862.2700 Nephelometer for clinical use.

* * * * *

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

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

§ 862.2730 Osmometer for clinical use.

* * * * *

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

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

§ 862.2750 Pipetting and diluting system for clinical use.

* * * * *

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

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

§ 862.2850 Atomic absorption spectrophotometer for clinical use.

* * * * *

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

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

§ 862.2860 Mass spectrometer for clinical use.

* * * * *

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

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

§ 862.2900 Automated urinalysis system.

* * * * *

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

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

§ 862.3280 Clinical toxicology control material.

* * * * *

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

97. Section 862.3750 is amended by revising paragraph (b) to read as follows:

§ 862.3750 Quinine test system.

* * * * *

(b) *Classification.* Class I.

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

§ 862.3850 Sulfonamide test system.

* * * * *

(b) *Classification.* Class I.

i.

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

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

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

100. Section 864.9 is revised to read as follows:

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

The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which

a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

(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 with respect to general requirements concerning records, and § 820.198 with respect to complaint files.

Handwritten note: A circled line connects the text "with respect to general requirements concerning records, and § 820.198 with respect to complaint files." to the handwritten text "of this chapter".

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:

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§ 864.6150 Capillary blood collection tube.

* * * * *

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

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

§ 864.9125 Vacuum-assisted blood collection system.

* * * * *

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

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

§ 864.9185 Blood grouping view box.

* * * * *

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

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

§ 864.9195 Blood mixing devices and blood weighing devices.

* * * * *

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

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

§ 864.9225 Cell-freezing apparatus and reagents for in vitro diagnostic use.

* * * * *

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

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

§ 864.9275 Blood bank centrifuge for in vitro diagnostic use.

* * * * *

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

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

§ 864.9320 Copper sulfate solution for specific gravity determinations.

* * * * *

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

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

§ 864.9750 Heat-sealing device.

* * * * *

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

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

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

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

113. Section 866.9 is revised to read as follows:

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

The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

(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 Cocksackievirus serological reagents.

* * * * *

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

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

§ 866.3200 Echinococcus spp. serological reagents.

* * * * *

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

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

§ 866.3240 Equine encephalomyelitis virus serological reagents.

* * * * *

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

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

§ 866.3355 Listeria spp. serological reagents.

* * * * *

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

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

§ 866.3360 Lymphocytic choriomeningitis virus serological reagents.

* * * * *

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

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

§ 866.3375 Mycoplasma spp. serological reagents.

* * * * *

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

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

§ 866.3380 Mumps virus serological reagents.

* * * * *

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

124. Section 866.3405 is amended by revising paragraph (b) to read as follows:

§ 866.3405 Poliovirus serological reagents.

* * * * *

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

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

§ 866.3480 Respiratory syncytial virus serological reagents.

* * * * *

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

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

§ 866.3500 Rickettsia serological reagents.

* * * * *

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

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

§ 866.3600 Schistosoma spp. serological reagents.

* * * * *

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

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

§ 866.3680 Sporothrix 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.

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

§ 866.5765 Retinol-binding protein immunological test system.

* * * * *

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

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

§ 866.5890 Inter-alpha trypsin inhibitor immunological test system.

* * * * *

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

PART 868—ANESTHESIOLOGY DEVICES

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

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

149. Section 868.9 is revised to read as follows:

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

The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

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

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

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

§ 868.1910 Esophageal stethoscope.

* * * * *

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

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

§ 868.5620 Breathing mouthpiece.

* * * * *

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

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

§ 868.5640 Medicinal nonventilatory nebulizer (atomizer).

* * * * *

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

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

§ 868.5675 Rebreathing device.

* * * * *

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

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

§ 868.5700 Nonpowered oxygen tent.

* * * * *

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

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

§ 868.6810 Tracheobronchial suction catheter.

* * * * *

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

PART 870—CARDIOVASCULAR DEVICES

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

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

157. Section 870.9 is revised to read as follows:

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

The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

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

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

158. Section 870.4200 is amended by revising paragraph (b) to read as follows:

§ 870.4200 Cardiopulmonary bypass accessory equipment.

* * * * *

(b) *Classification.* Class I.

PART 872—DENTAL DEVICES

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

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

160. 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 Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

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

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

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

§ 872.3275 Dental cement.

(a) * * *

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

* * * * *

162. 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.

* * * * *

163. 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.

* * * * *

164. Section 872.6300 is amended by revising paragraph (b) to read as follows:

§ 872.6300 Rubber dam 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 § 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, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

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

§ 872.6390 Dental floss.

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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 § 872.9.

166. 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

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

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

168. 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 Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

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

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

169. 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.

170. 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.

171. 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, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

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

§ 874.1800 Air or water caloric stimulator.

* * * * *

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

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

§ 874.1925 Toyntee 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.

174. 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.

175. 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, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

176. 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.

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177. 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.

178. 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.

179. 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.

180. 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

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

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

182. 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 Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

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

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

183. Section 876.5160 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.

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

§ 876.5210 Enema kit.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter,

with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

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

§ 876.5250 Urine collector and accessories.

* * * * *

(b) * * *

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

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

§ 876.5980 Gastrointestinal tube and accessories.

* * * * *

(b) * * *

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

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

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

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

188. 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 Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

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

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

189. 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.

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

§ 878.3910 Noninflatable extremity splint.

* * * * *

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

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

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§ 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.

192. 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.

193. 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.

194. 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.

195. 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.

196. 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.

197. 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.

198. 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.

199. 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

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

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

201. 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 Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

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

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

202. 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.

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203. 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, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

204. 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

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

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

206. 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 Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could

significantly affect a device's safety or effectiveness, 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 and 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) 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;

- (8) For noninvasive testing as defined in § 812.3(k) of this chapter; and
- (9) For near patient testing (point of care).

207. 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, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

208. 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, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

209. 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.

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

§ 882.4060 Ventricular cannula.

* * * * *

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

211. 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.

212. 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.

213. 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

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

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

215. 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 Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

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

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

216. 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.

PART 886—OPHTHALMIC DEVICES

217. The authority citation for 21 CFR part 886 continues to read as follows:

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

218. Section 886.9 is revised to read as follows:

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

The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;
- (8) For noninvasive testing as defined in § 812.3(k) of this chapter; and
- (9) For near patient testing (point of care).

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

§ 886.1780 Retinoscope.

* * * * *

(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, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

220. 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.

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221. 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.

222. 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.

223. 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, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

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

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§ 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

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

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

226. 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 Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

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

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

PART 890—PHYSICAL MEDICINE DEVICES

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

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

228. 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 Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

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

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

229. Section 890.1175 is amended by revising paragraph (b) to read as follows:

§ 890.1175 Electrode cable.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9. The devices are exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

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

§ 890.5180 Manual patient rotation bed.

* * * * *

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

231. Section 890.5710 is amended by revising paragraph (b) to read as follows:

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§ 890.5710 Hot or cold disposable pack.

* * * * *

(b) *Classification.* Class I (general controls). Except when intended for use on infants, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

PART 892—RADIOLOGY DEVICES

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

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

233. Section 892.9 is revised to read as follows:

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

The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, 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 and 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) 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;

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

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

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

§ 892.1300 Nuclear rectilinear scanner.

* * * * *

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

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

§ 892.1320 Nuclear uptake probe.

* * * * *

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

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

§ 892.1330 Nuclear whole body scanner.

* * * * *

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

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

§ 892.1350 Nuclear scanning bed.

* * * * *

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

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

§ 892.1410 Nuclear electrocardiograph synchronizer.

* * * * *

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

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

§ 892.1890 Radiographic film illuminator.

* * * * *

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

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

§ 892.1910 Radiographic grid.

* * * * *

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

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

§ 892.1960 Radiographic intensifying screen.

* * * * *

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

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

§ 892.1970 Radiographic ECG/respirator synchronizer.

* * * * *

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

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

§ 892.2010 Medical image storage device.

* * * * *

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

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

§ 892.2020 Medical image communications device.

* * * * *

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

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

§ 892.5650 Manual radionuclide applicator system.

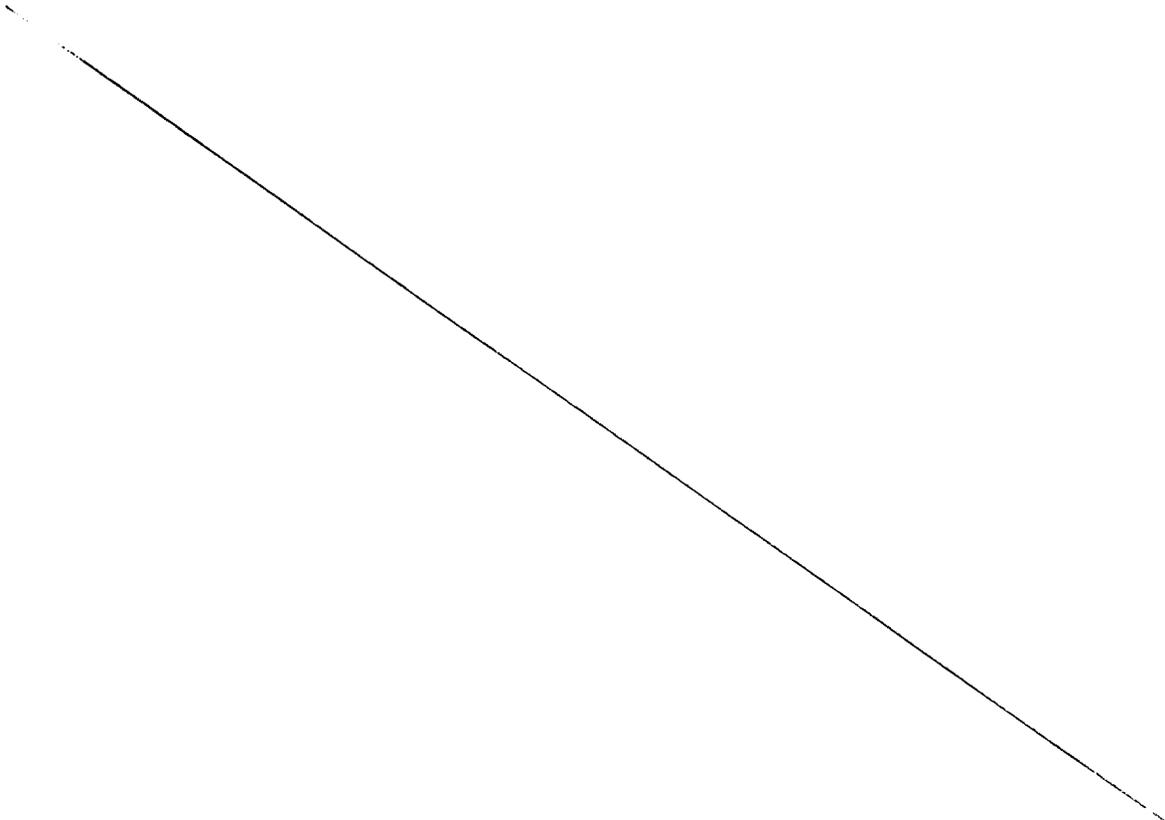
* * * * *

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

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

§ 892.6500 Personnel protective shield.

* * * * *



(b) *Classification.* 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: October 14, 1998
October 14, 1998

William B. Schultz
William B. Schultz
Deputy Commissioner for Policy

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

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