Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff

This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Premarket Notification (510(k)) Staff, Program Operations Staff (POS), Office of Device Evaluation

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Until May 26, 1998, comments and suggestions regarding this document should be submitted to Docket No. 98D-0083, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 12420 Parklawn Drive (HFA-305), Room 1-23, Rockville, MD 20857. Such comments will be considered when determining whether to amend the current guidance.

After May 26, 1998, comments and suggestions may be submitted at any time for Agency consideration to, **Heather Rosecrans, Chief, Premarket Notification Staff, HFZ-404, 9200 Corporate Blvd., Rockville, MD 20850.** Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact **Heather Rosecrans at 301-594-1190.**

Additional Copies: World Wide Web/CDRH home page at http://www.fda.gov/cdrh or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number **159** when prompted for the document shelf number.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Rockville, MD 20850

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I. Purpose

The purpose of this guidance[1] is to establish standard operating procedures for the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) to carry out Section 510(m)(2) of the Federal Food, Drug, and Cosmetic Act (the Act), as amended by Section 206 of the FDA Modernization Act of 1997 (FDAMA). This FDAMA amendment provides that interested persons may petition FDA to exempt class II device types, as defined in 21 CFR 860.3(i), from the premarket notification requirements of section 510(k) of the Act.

II. Background

As provided by FDAMA, FDA exempted through a FEDERAL REGISTER (FR) notice, 62 class II device types from premarket notification (section 510(k)) requirements on January 21, 1998 (63 FR 3142). Beginning on January 22, 1998, (1 day after the date of the publication in the FR of the list of class II devices exempt from premarket notice), FDA, upon its own initiative or upon a petition of an interested person, may exempt a class II device from premarket notification requirements under section 510(m)(2). This may be done if FDA finds that a premarket notification for the class II device type is not necessary to assure the safety and effectiveness of the device. Before granting an exemption, FDA must publish a notice in the FR of the petitioner's request or of FDA's intent to exempt the class II device type. The FR notice will provide a 30-day period for public comment. In addition, within 120 days of this FR notice requesting comment, FDA will publish an order in the FR of its final determination regarding the exemption of the device type. If FDA receives a petition requesting exemption from premarket notification for a class II device type and does not respond within 180 days of receipt of such a petition, the exemption will be deemed effective by operation of the statute.

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III. Factors FDA May Consider for Exemption

In its January 21, 1998 FR notice (63 FR 3142), FDA described the criteria the agency had used to determine which class II device types should be exempt from the premarket notification (510(k)) requirements. The FR notice stated:

> "In considering whether to exempt class II devices from premarket notification, FDA focused on whether premarket notification for the type of device is necessary to provide reasonable assurance of safety and effectiveness of the device. FDA considered the following factors: (1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials (when making these determinations, FDA has considered the risks associated with false or misleading claims, and the frequency, persistence, cause or seriousness of the inherent risks of the device); (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either: (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, e.g., testing of a clinical laboratory reagent with positive and negative controls; or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA also considered that even when exempting devices, these devices would still be subject to the limitations on exemptions, as described in section III of this document."

The agency believes these factors should also be considered when determining if any additional class II device type(s) should be exempted from 510(k) requirements. Among these factors the agency believes are important for special consideration are the "Limitations on Exemptions," a copy of which is found in the Attachment with this document. Likewise, a petition by an interested person for exemption for a class II device type should clearly address the factors described above so the agency and respondents can expeditiously consider whether to concur in the request.

IV. Standard Operating Procedures (SOPs)

A petition requesting that a class II device type be exempt from section 510(k) under 21 CFR 10.30 must be submitted to Dockets Management Branch, HFA-305, Food and Drug Administration, Dept. of Health and Human Services, Room 1-23, 12420 Parklawn Drive, Rockville, MD 20857. We also request that the petitioner send a copy to CDRH's Document Mail Center (HFZ-401), 9200 Corporate Blvd., Rockville, MD 20850. The petitioner should state prominently on the outside of the envelope, the inside cover, if any, and the cover sheet "Class II 510(k) exemption petition". The

petition must include information described in 10.30(b). The petitioner should identify the device classification name, regulation number, the petitioner's name, address, telephone and fax number, and clearly address why the petitioner believes premarket notification requirements are not necessary to assure safety and effectiveness for the device type. The petitioner is requested to specifically address the factors enumerated under Section III of this document.

Upon receipt of a petition, the Dockets Management Branch will date stamp the petition. This stamped FDA receipt date will serve to start the 180-day time period for FDA to respond to the petition.

FDA will publish an **FR** notice announcing the petition, or of FDA's intent to exempt a device type on its own initiative, and provide a 30-day comment period. FDA will review any Medical Device Reports (MDRs) and recalls for the device type, obtain advisory panel input, as needed, and review any comments received in response to the **FR** notice. Once the agency determination regarding the exemption of the device type has been made, FDA will publish an order in the **FR** announcing the final determination. This should publish within 180 days of receipt of any such petition.

Special Notes

1. At any time during the review of a petition to request exemption from 510(k), FDA may request clarification from the petitioner. However, if the petitioner wishes to amend the petition by submission of additional information, FDA will generally consider it to be a new petition and it will restart the 180-day clock.

2. The exemptions from the premarket notification requirements may be subject to certain limitations. For example, FDA may exempt a device provided that it bear certain labeling statements, or provided that it meet certain testing requirements. Devices that do not meet these requirements would not be considered exempt from premarket notification requirements and would be required to submit premarket notifications and obtain FDA clearance prior to marketing.

Attachment

Limitations on Exemptions

The exemption from the requirement of premarket notification for a generic type of device listed in this document applies only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. Accordingly, a class II device listed in this document is not exempt if such device: (1) has an intended use that is different from the intended use of a legally marketed device in that generic type; e.g., the device is intended for a different medical purpose, or the device is intended for lay use instead of use by health care professionals; or (2) operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type; 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 a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization or amplification technology rather than culture or immunoassay technology; or (3) is an in vitro device: that is intended for use in the diagnosis, monitoring or screening of neoplastic diseases with the exception of immunohistochemical devices; is intended for use in screening or diagnosis of familial and acquired genetic disorders, including inborn errors of metabolism; is intended for measuring an analyte which 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; is intended to assess the risk of cardiovascular diseases; is intended for use in diabetes management; is intended to identify or infer the identity of a microorganism directly from clinical material; is intended 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; uses noninvasive testing; is intended for near-patient testing (point of care).

Class II devices incorporating such changes or modifications are not exempt from premarket notification because FDA has determined that premarket notification is necessary to assure the safety and effectiveness of the device.

In addition to the general limitation on exemptions that applies to all class II devices that are described previously, FDA may limit the exemption from premarket notification requirements to certain devices within a generic

class. For example, FDA is listing the exemption of the biofeedback device, but limits the exemption to prescription battery powered devices that are indicated for relaxation training and muscle reeducation. All other biofeedback devices are still subject to premarket notification requirements because FDA determined that premarket notification was necessary to provide a reasonable assurance of safety and effectiveness for these devices.

FDA advises, additionally, 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. Indeed, FDA's determination that premarket notification was unnecessary to provide a reasonable assurance of safety and effectiveness for devices listed in this document is based, in part, on the assurance of safety and effectiveness that other regulatory controls, such as current good manufacturing practice requirements, provide.