Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff (Update to K98-1)

Document issued on: December 3, 2002

This document supersedes Determination of Intended Use for 510(k) Devices; Guidance for Industry and CDRH Staff issued January 30, 1998

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Device Evaluation
and
Office of In Vitro Diagnostic Device Evaluation and Safety

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to Docket No. 98D-0081. 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 the Premarket Notification (510(k)) Section at 301-796-5640.

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Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff

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

Purpose

The primary purpose of this guidance document is to reflect the elimination of the sunset provision of Section 513(i)(1)(E) of the Federal Food, Drug, and Cosmetic Act (the Act). The sunset provision was eliminated by Section 208 of the Medical Device User Fee and Modernization Act (MDUFMA) of 2002, permitting Center for Devices and Radiological Health (CDRH) staff to continue following established procedures for the determination of intended use in 510(k) submissions.

This guidance also updates our procedures to include minor changes we have instituted since Section 513(i)(1)(E) was implemented. Additionally, we have revised the title to clarify that these procedures, although they affect industry, are CDRH staff procedures. This guidance supersedes **Determination of Intended Use for 510(k) Devices; Guidance for Industry and CDRH Staff**, issued January 30, 1998.

Background

As stipulated in Section 513(i) of the Act, FDA may issue an order of substantial equivalence only upon making the determination that the device to be introduced into commercial distribution has the same intended use as the predicate device and is as safe and effective as a legally marketed device. Section 513(i)(1)(E) of the Act generally limits the determination of the intended use of a device that is the subject of a premarket notification (510(k)) to the proposed labeling contained in the submission.

"Labeling" is defined in Section 201(m) of the Act as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for use are required to be submitted in a 510(k) for review during the substantial equivalence determination. (See 21 CFR 807.87(e))

Thus, based on the above, the intended use of a device is determined by an evaluation of the proposed labeling for the device as submitted in the 510(k). As stated in ODE Blue

Book Memorandum #K86-3 entitled **Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program** (June 30, 1986) http://www.fda.gov/cdrh/k863.html, "Ordinarily, intended use is determined by reference to 'labeling' or promotional claims; only in rare cases might it be necessary to infer intended use from other types of information."

In addition to the restrictions regarding the determination of intended use, the law defines the procedures to be followed if the Office Director believes "that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device" and "that such use could cause harm." (See Section 513(i)(1)(E)(ii)). These procedures are described below.

Procedures

A. Procedures for Division Staff

In determining the intended use of a device that is the subject of a 510(k), reviewers should continue to follow Blue Book #K86-3 guidance, which states that the intended use of the device should be determined by the proposed labeling for the product. As defined above, this includes the actual label for the device and any accompanying information such as directions for use and promotional materials.

In reviewing the premarket notification, there may be rare instances in which the design of the device or published literature referencing the subject device or a similar device, would lead one to believe that there may be an intended use different than that appearing in the labeling. If this situation occurs, the reviewer should bring the discrepancy to the attention of senior division management.

The reviewer and division management should consider:

- Whether there is a **reasonable likelihood** that the device will be used for an intended use not identified in the proposed labeling for the device, **and**

- if such use **could cause harm** to the patient or the consumer.

If, while reviewing the 510(k), the division makes the determination that there is a reasonable likelihood that the device will be used for an intended use other than that in the proposed labeling (hereinafter referred to as off-label use) that could cause harm, the review of the submission should proceed as follows. The reviewer should discuss all deficiencies with regard to the submission, except those regarding the off-label use, with the firm and resolve the deficiencies in accordance with established division procedures. Once all other outstanding issues have been resolved, the reviewer should promptly bring the concern about the off-label use to the attention of the Chief of the Premarket Notification Section (Chief), Program Operations Staff (POS). The Chief will be responsible for coordinating the resolution of the off-label use issue with the appropriate Office Director. If, while reviewing the 510(k), the reviewer observes no deficiencies that prevent a substantial equivalence

recommendation other than the concern regarding an off-label use, the division should bring that concern to POS as soon as the review of the 510(k) is complete.

Devices that are substantially equivalent to legally marketed devices that have limitations regarding off-label use imposed by the Office Director under Section 513(i)(1)(E) should be subject to the same limitations. Review divisions should be vigilant in identifying devices that fall within this category. When a review division encounters a device that should be subject to the same limitations regarding off-label use as the predicate, the review division should retrieve a copy of the predicate device's "substantially equivalent (SE) with limitations" letter and forward it with the submission to POS as described above.[1]

B. Procedures for the Office Director

When the Office Director receives a referral from POS regarding off-label use, the Office Director will evaluate the information provided and determine if the two statutory criteria are met. That is, the Office Director must decide (1) if there is a **reasonable likelihood** that the device will be used for an intended use not identified in the proposed labeling **and** (2) if such use **could cause harm** to the user.[2] If the Office Director determines that these criteria are not met, the Office Director should document the discussion and the Office should promptly issue a "substantially equivalent" (SE) letter. If, however, the Office Director believes that the two criteria are met, the 510(k) submitter will have an opportunity for consultation.

Consultation

Consultation between the Office Director and the 510(k) submitter may take the form of a telephone call or a meeting. The form of the consultation will depend the needs of both parties and the most expedient path to resolution.

Resolution

Following consultation, one of three actions may ensue.

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[1] When this situation is encountered, CDRH has determined that the most expedient course of action is for POS to send a draft "SE with limitations" letter to the submitter of the pending 510(k). The letter will propose the identical limitations imposed by the Office Director on the predicate device. The submitter will have an opportunity to assent or to request a telephone call or meeting with the Office Director, in accordance with the procedures outlined in the "Consultation" section of this memorandum. In cases where the submitter assents to the proposed limitations, the Office Director will immediately issue a final order.

[2] For purposes of this document, the term "user" may be the patient, health care provider, or any other person who has the device used on or in himself/herself or who uses the device him/herself.

First after discussing the off-label use issue with the firm, the Office Director may decide that the two criteria regarding off-label use have not been met and direct the division to issue a substantial equivalence determination.

Alternatively, if the Office Director believes that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling and that this use could cause harm, the firm will have an opportunity to:

- modify the device design to address the off-label use; **or**
- request a written determination from the Office Director.

If the modified design satisfies the Agency's concerns regarding the off-label use, the division will issue a substantially equivalent determination.

Finally, if the firm either fails to modify the device or decides to request a written determination from the Office Director, the Office Director will issue an "SE with limitations" letter within 10 days of the consultation.

The "SE letter with limitations" letter (the letter) will advise the 510(k) submitter that the Office Director has determined that:

- there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and
- such use could cause harm.

The letter will specify appropriate limitations regarding the off-label use to be included in the labeling for the device. These labeling limitations may be expressed using the standardized language provided in the boilerplate letters[3] or may include other labeling limitations specific to the device and the off-label use, as determined by the Office Director. The letter will require these limitations to be added to the Precautions, Warnings, Contraindications, or other appropriate section of the device's labeling. Finally, the letter will stipulate that the device is only substantially equivalent if the labeling for the device conforms to the limitations specified in the letter.

Special Notes

As stipulated in Section 513(i)(1)(E) of the Act, the Office Director may not delegate any of the responsibilities specified in this memorandum.

According to ODE Blue Book #K97-1 entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" http://www.fda.gov/cdrh/ode/510kmod.html, manufacturers are permitted to make certain labeling changes without submission of a

[3] The boilerplates "SE letter with Limitations" were drafted for use under the conditions described above. Both Office of Device Evaluation (ODE) and Office of In Vitro Diagnostic Devices Evaluation and Safety (OIVDES) "SE with Limitations" boilerplates, K-32 and K-32A, respectively, are available to CDRH staff on the shared drive H:\.

new 510(k). The labeling limitations included in the "SE letter with Limitations," however, are required by Section 513(i)(1)(E) of the Act. Therefore, a manufacturer must submit a new 510(k) before these limitations are modified in any way or removed from the device's labeling.