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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 884

Classification of the Breast Lesion Documentation System and Notice of Availability of Guidance Document; Final Rule and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. 2003P–0301]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Breast Lesion Documentation System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the breast lesion documentation system into class II (special controls). The special controls that will apply to this device are discussed later in this document. The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997 (FDAMA). The agency is classifying this device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document that is the special control for this device.

DATES: This rule is effective August 27, 2003.

FOR FURTHER INFORMATION CONTACT: Colin Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the amendments, generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the FDA regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.

On May 28, 2002, FDA received a petition submitted under section 513(f)(2) of the act by Assurance Medical, Inc., through Hogan & Hartson, L.L.P., seeking an evaluation of the automatic class III designation of its BREASTVIEW Visual Mapping System. In accordance with section 513(f)(1) of the act, FDA issued an order on April 30, 2002, automatically classifying the BREASTVIEW Visual Mapping System in class III because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or II. After reviewing information submitted in the petition, FDA determined that the BREASTVIEW Visual Mapping System can be classified in class II with the establishment of special controls. This device is intended for use in producing a surface map of the breast as an aid to document palpable breast lesions identified during a clinical breast exam. FDA believes that class II special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

FDA has identified the following risks to health associated specifically with this type of device: (1) Failure to produce an appropriate map, (2) misinterpretation of displayed images, (3) improper use, (4) skin irritation or toxicity, (5) electrical shock, (6) electromagnetic interference, and (7) tissue trauma from mechanical injury. Therefore, in addition to the general controls of the act, the device is subject to a special controls guidance document entitled ''Class II Special Controls Guidance Document: Breast Lesion Documentation System.''

The class II special controls guidance provides information on how to meet premarket (510(k)) submission requirements for the device, including recommendations for labeling, information on material safety, performance characteristics, bench testing, and software information. FDA believes that adherence to the class II special controls addresses the risks to health identified previously and provides a reasonable assurance of the safety and effectiveness of the device. Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a breast lesion documentation system will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirement under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness and, therefore, the device is not exempt from the premarket notification requirements. The device is used in producing a surface map of the breast as an aid to document palpable breast lesions identified during a clinical breast exam. FDA review of key design features, data sets from bench studies and clinical trials, other relevant performance data, and labeling will ensure that acceptable levels of performance for both safety and effectiveness are addressed before marketing clearance. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the breast lesion documentation system before marketing the device.

On January 31, 2003, FDA issued an order classifying the BREASTVIEW Visual Mapping System and substantially equivalent devices of this generic type into class II under the generic name, breast lesion documentation system. FDA identifies this generic type of device as a breast lesion documentation system, which is intended for use in producing a surface map of the breast as an aid to document

palpable breast lesions identified during a clinical breast exam.

FDA is codifying this device by adding § 884.2990. The order also identifies a special control applicable to this device, a guidance document entitled ''Class II Special Controls Guidance Document: Breast Lesion Documentation System'' For the convenience of the reader, FDA is also adding § 884.1(e) to inform the reader where to find guidance documents referenced in 21 CFR part 884.

II. Electronic Access

In order to receive the guidance entitled ''Class II Special Controls Guidance Document: Breast Lesion Documentation System'' via your fax machine, call the CDRH Facts-on-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1202) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of cleared/approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at *http://www.fda.gov/cdrh*.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so it is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA knows of only one manufacturer of this type of device. Classification of these devices from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs. The agency, therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 884

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

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

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

■ 2. Section 884.1 is amended by adding paragraph (e) to read as follows:

§ 884.1 Scope.

* * * * *

(e) Guidance documents referenced in this part are available on the Internet at *http://www.fda.gov/cdrh/guidance.html.*

■ 3. Section 884.2990 is added to subpart C to read as follows:

§ 884.2990 Breast lesion documentation system.

(a) *Identification.* A breast lesion documentation system is a device for use in producing a surface map of the breast as an aid to document palpable breast lesions identified during a clinical breast examination.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance entitled ''Class II Special Controls Guidance Document: Breast Lesion Documentation System.'' See § 884.1(e) for the availability of this guidance document.

Dated: July 17, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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