

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.

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**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

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