3. All public comments on this advanced notice of proposed rulemaking will be a matter of public record and will be available for public inspection and copying. (Communications from agencies of the United States Government or foreign governments will not be made available for public inspection).

4. In the interest of accuracy and completeness, the Department requires comments in written form. Oral comments must be followed by written memoranda which will also be a matter of public record and will be available for public review and copying.

5. The Department will *not* accept public comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such comments and materials to the person submitting the comments and will *not* consider them in the development of final regulations, and;

6. The comments received in response to this notice will be maintained in the Bureau of Export Administration, Freedom of Information Records Inspection Facility, Room 4525, Department of Commerce, 14th Street and Pennsylvania Avenue, N.W., Washington, DC 20239. Interested parties may inspect and copy records in this facility, including written public comments and memoranda summarizing the substance of oral communications, in accordance with regulations published in Part 4 of Title 15 of the Code of Federal Regulations. Information about the inspection and copying of records may be obtained from Margaret Cornejo, Bureau of Export Administration, Management Analyst, at the above address or by calling (202) 482 - 5653.

### **Rulemaking Requirements**

The rule which is likely to be proposed based on this notice was determined to be significant under Executive Order 12866.

Dated: June 2, 1995.

### Sue E. Eckert,

Assistant Secretary for Export Administration.

[FR Doc. 95–14038 Filed 6–6–95; 8:45 am]

BILLING CODE 3510-DT-P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# Food and Drug Administration

### 21 CFR Part 872

[Docket No. 95N-0033]

# Dental Devices; Effective Date of Requirement for Premarket Approval of Endodontic Dry Heat Sterilizer

AGENCY: Food and Drug Administration, HHS.

**ACTION:** Proposed rule; opportunity to request a change in classification.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the endodontic dry heat sterilizer, a medical device. The agency also is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the statute's approval requirements, and the benefits to the public from use of the device. In addition, FDA is announcing the opportunity for interested persons to request the agency to change the classification of the device based on new information.

DATES: Written comments by September 5, 1995; requests for a change in classification by June 22, 1995. FDA intends that, if a final rule based on this proposed rule is issued, PMA's will be required to be submitted within 90 days of the effective date of the final rule. ADDRESSES: Submit written comments or requests for a change in classification to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594– 4765.

### SUPPLEMENTARY INFORMATION:

## I. Background

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. For the sake of convenience, this preamble refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date as "preamendments devices."

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, a preamendments device, subject to the rulemaking procedure under section 515(b) of the act, is not required to have an approved investigational device exemption (IDE) (21 CFR part 812) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device.

Section 515(b)(2)(A) of the act provides that a proceeding to issue a final rule to require premarket approval shall be initiated by publication of a notice of proposed rulemaking containing: (1) The proposed rule; (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device; (3) an opportunity for the submission of comments on the proposed rule and the proposed findings; and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change of classification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. If FDA does not initiate such a proceeding, section 515(b)(3) of the act provides that FDA shall, after the close of the