

that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that 1 day after date of publication of the list under section 510(m)(1) of the act, FDA may exempt a device on its own initiative, or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a Class II device. These factors are discussed in the guidance that the agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff." That guidance can be obtained through the Internet on the CDRH home page at <http://www.fda.gov/cdrh.guidance.html> or by facsimile through CDRH Facts-on-Demand at 1-800-899-0381 or 301-827-0111. Specify "159" when prompted for the document shelf number.

III. Petition

On October 25, 2002, FDA received a petition requesting an exemption from premarket notification for data acquisition units for ceramic dental restoration systems. These devices are currently classified under § 872.3660 *Impression material* (21 CFR 872.3660) as an accessory. In the **Federal Register** of January 30, 2003 (67 FR 2787), FDA published a notice announcing that this petition had been received and provided opportunity for interested persons to submit comments on the petition by March 3, 2003. FDA did not receive any comments.

FDA has determined that maintaining classification of the data acquisition units in Class II and exempting them from the premarket notification requirements, with the guidance document as a special control, will provide reasonable assurance of the safety and effectiveness of these devices and, therefore, they meet the criteria for

exemption from the premarket notification requirements. For precision and clarity, FDA is: (1) Designating these devices as "optical impression systems for computer assisted design and manufacturing (CAD/CAM);" (2) placing them in new § 872.3661; (3) exempting them from the premarket notification requirements; and (4) establishing the guidance document entitled "Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA" as the special control for these devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of this guidance document. Following the effective date of this final rule any firm submitting a 510(k) premarket notification for an optical impression system for CAD/CAM 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. All other devices classified under § 872.3660 will continue to be classified in that section and subject to the same regulatory requirements as before.

For the benefit of the reader, FDA is also adding a § 872.1(e) to direct the reader to the Web site for guidance documents.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

V. 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 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. This rule will relieve a burden and simplify the marketing of these devices. The guidance document is based on existing review practices and will not impose any new burdens on these devices. The agency, therefore, certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Paperwork Reduction Act of 1995

FDA concludes that 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.

VII. 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 order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 872

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 872 is amended as follows:

PART 872—DENTAL DEVICES

■ 1. The authority citation for 21 CFR part 872 continues to read as follows:

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

■ 2. Section 872.1 is amended by adding paragraph (e) to read as follows:

§ 872.1 Scope.

* * * * *