

address the risks of device failure. Adherence to the recommended standards can mitigate the risk of device failure, e.g., PFM deforming, cracking, or debonding because of biocompatibility.

Another consensus standard identified in the special controls guidance recommends biocompatibility testing. Adherence to this standard can mitigate the risk of adverse tissue reaction by ensuring that the device materials are sufficiently biocompatible for use as permanent implants.

The labeling information provided in the guidance documents addresses the risk of improper use by recommending that manufacturers, in addition to complying with the general labeling provisions of 21 CFR part 801, include indications for use and contraindications for individuals with nickel hypersensitivity in their labeling.

FDA believes that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of these devices and, therefore, is giving notice of its intent to exempt the devices from that requirement if the recommendations of the special controls guidance are met.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the draft guidance documents that would serve as the special controls for these devices.

VI. 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.

VII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed 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. The purpose of this proposed rule is to designate a special control for these devices. FDA has designated guidance documents as the special controls. FDA believes that manufacturers, including small manufacturers, are already substantially in compliance with the recommendations in the guidance documents and they will not add substantially to the information manufacturers presently submit. FDA, therefore, believes that the rule will impose no significant economic impact on any small entities. The agency, therefore, certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. In addition, this proposed 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 or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VIII. Paperwork Reduction Act of 1995

This proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

IX. Submission of Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this proposed rule. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. Proposed Implementation Plan

FDA proposes that any final regulation that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**. Following the effective date of a final rule exempting the device, manufacturers of dental precious metal alloy and base metal alloy devices will need to address the issues covered in

these special controls guidances. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness. If manufacturers cannot comply with these recommendations or equivalent measures, they will not be exempt from the requirements of premarket notification and will need to submit a premarket notification and receive clearance for their device prior to marketing.

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, it is proposed that 21 CFR part 872 be 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 revising paragraph (e) to read as follows:

§ 872.1 Scope.

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(e) Guidance documents in this part may be obtained on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

3. Section 872.3060 is amended by revising paragraph (b) to read as follows:

§ 872.3060 Gold-based alloys and precious metal alloys for clinical use.

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(b) *Classification.* Class II (special controls). The special control for these devices is FDA's "Class II Special Controls Guidance Document: Dental Precious Metal Alloys." The devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. (See § 872.1(e) for availability of guidance information.)

4. Section 872.3710 is amended by revising paragraph (b) to read as follows:

§ 872.3710 Base metal alloy.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Dental Base Metal Alloys." The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. (See § 872.1(e) for availability of guidance information.)