Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Dental Base Metal Alloys

GUIDANCE

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This guidance supersedes Guidance Document for the Preparation of Premarket Notifications [510(k)'s] for Dental Alloys, issued March 3, 1997.

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. When submitting comments, please refer to Docket No. 2003D-0391. Comments may not be acted upon by the Agency until the document is next revised or updated.

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Background

FDA is designating this guidance document as a special control to exempt dental base metal alloys from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (the Act). FDA is issuing this guidance in conjunction with a Federal Register notice announcing the final rule.

This guidance document describes a means by which dental base metal alloy devices may comply with the requirement of Class II Special Controls. Designation of this guidance document as a special control means that manufacturers of dental base metal alloy devices who follow the recommendations listed in this document, before introducing their device into commercial distribution in the United States, will be able to market their device without being subject to the premarket notification requirements of section 510(k) of the Act.

Section 510(m) of the Act provides that FDA may exempt a class II device from the premarket notification requirements 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. FDA has determined premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of this generic type of device if the manufacturer follows the recommendations in this special controls guidance or equivalent measures to address the risks identified in this guidance. Thus, persons who intend to market a device of this type do not need to submit a premarket notification to FDA and receive agency clearance prior to marketing the device, but as a class II device, the device must comply with the general and special controls (Section 513(a)(1)(B)).

Following the effective date of the final rule exempting the device, manufacturers of dental base metal alloy devices will need to address the issues covered in this special control guidance. 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.[1] 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.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the guidance, **A Suggested Approach to Resolving Least Burdensome Issues,** http://www.fda.gov/cdrh/modact/leastburdensome.html

2. Scope

FDA identifies a dental base metal alloy as a device, classified under 21 CFR §872.3710 below:

Sec. 872.3710 Base metal alloy.

(a) Identification. A base metal alloy is a device composed primarily of base metals, such as nickel, chromium, or cobalt, that is intended for use in fabrication of cast or porcelain-fused-to metal crown and bridge restorations.

(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; Guidance for Industry and FDA." 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.

[1]We recommend that you document how you have addressed the recommendations in your design history file. Manufacturers must maintain design controls, including a design history file, in accordance with 21 CFR 820.30.

A base metal alloy may be primarily composed of chromium, cobalt, or nickel, with lesser amounts of other elements such as molybdenum and aluminum. The device is intended to fabricate:

- all-metal (cast) dental appliances such as crowns and bridges; or
- the coping or substrate to which is fused a ceramic coating for fabricating dental appliances such as crowns and bridges.

This classification includes cast and porcelain-fused-to-metal (PFM) cobalt-chromium, nickel-chromium, and titanium alloys and solders. The product code associated with this classification identification is EJH - Metal, Base.

The scope of this guidance does not include:

- alloys for dental implants, wrought alloys for orthodontic wires, and other alloys for dental instruments which are classified elsewhere under 21 CFR.872.3640, 3980, 5410, and 4565
- noble metal alloys which are addressed in the guidance entitled, **Class II Special Controls Guidance Document: Dental Noble Metal Alloys**, http://www.fda.gov/cdrh/ode/guidance/1415.pdf
- mercury amalgam alloys or dental mercury which are classified elsewhere under 21 CFR 872.3050 and 3700, respectively.

3. Risks to Health

FDA has identified the following risks to health associated with the use of the dental base metal alloys in the tables below, depending on whether the device is a casting metal alloy or a PFM alloy. FDA recommends the following measures to mitigate the identified risks in this guidance, as shown in the tables below.

Casting Alloys

Identified Risks	Recommended Mitigation Measures
Device failure	Section 4. Mechanical Properties for Casting Alloys
Adverse tissue reaction	Section 6. Biocompatibility
Improper use	Section 7. Labeling

PFM Alloys

Identified Risks	Recommended Mitigation Measures
Device failure	Section 5. Mechanical Properties for PFM Alloys
Adverse tissue reaction	Section 6. Biocompatibility
Improper use	Section 7. Labeling

The mechanical properties of the device may be insufficient to support the required loads and lead to device failure. Porcelain may deform, crack, and debond from the metal because of incompatibilities. Some alloy compositions may also be susceptible to corrosion. These device failures may result in ineffective treatment, revision, and possibly minor, temporary impairment for the patient.

Some alloy compositions may not be biocompatible. Poor biocompatibility may result in adverse tissue reaction.

Inadequate labeling may result in improper use. Improper use may result in ineffective treatment and may cause minor, temporary impairment for the patient.

4. Mechanical Properties for Casting Alloys

We recommend that base metal casting alloys conform to the FDA- recognized standard below.

- **American National Standard/American Dental Association Specification No. 14-1998, "Dental Base Metal Casting Alloys"** (ANSI/ADA Specification No. 14)

In particular, Table 1 of the ANSI/ADA Specification No. 14 specifies the minimum mechanical properties for casting alloys. Section 3.1 of this standard specifies compositions resistant to corrosion. Section 3.2.1.1 of this standard specifies that no visible signs of corrosion should be seen for one year when exposed to an oral environment.

For base metal solders (brazing alloys), we recommend conformance to the FDA-recognized standard below.

- **American National Standard/American Dental Association Specification No. 88-2000, "Dental Brazing Alloys"** (ANSI/ADA Specification No. 88)

In particular, section 4.5 of ANSI/ADA Specification No. 88 specifies the minimum mechanical properties for solders.

5. Mechanical Properties for PFM Alloys

We recommend that base metal PFM alloys conform to the FDA-recognized standard below.

- **American National Standard/American Dental Association Specification No. 38-2000, "Metal-Ceramic Dental Restorative Systems"** (ANSI/ADA Specification No. 38)

In particular, Table 1 of the ANSI/ADA Specification No. 38 specifies the minimum mechanical properties of the metal. Table 2 of this standard specifies the minimum

mechanical properties of the porcelain for these metals. Section 4.3.3 of this standard specifies the minimum bond compatibility index between the metal and porcelain.

6. Biocompatibility

We recommend that you insure the biocompatibility of your device by complying with the tests in the following standard for a permanent contact, external communicating device on tissue, bone, or dentin in accordance with the applicable requirements of ISO-10993 (instead of ANSI/ADA Specification No. 41, which is incorporated by reference in ADA Specification No. 14). See Blue Book Memorandum #G95-1, entitled "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," http://www.fda.gov/cdrh/g951.html, for additional guidance on the use of ISO-10993.

7. Labeling

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use.[2] In conformance with section 3.4.2 of ANSI/ADA Specification No. 14, we recommend that you include at caution statement for nickel hypersensitive individuals, if the alloy composition contains >1% Ni.

8. Limitations of Exemption from Premarket Notification

FDA's decision to exempt a Class II device from the requirement of 510(k) is based on the existing and reasonably foreseeable characteristics of devices within that generic type that currently are, or have been, in commercial distribution. Section 21 CFR 872.9 specifies the limitations to exemption. A device classified as exempt from 510(k) requirements is not exempt, if the device:

- is for an intended use that is different from the intended use of a legally marketed device in that generic type
- operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type.

If any of these limitations apply, your device is not exempt and you must submit a 510(k).

[2] Final labeling must comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce.