As of January 31, 2018, over-the-counter denture repair kits (Product Code EBO, 21 CFR 872.3570) are exempt from premarket notification (510(k)). Please refer to the Federal Register of March 14, 2018 (Docket No. FDA-2017-P-5124) for more information.

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Guidance for Industry and FDA Staff

OTC Denture Cushions, Pads, Reliners, Repair Kits, and Partially Fabricated Denture Kits

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U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Dental Devices Branch
Division of Dental, Infection Control, and General Hospital Devices
Office of Device Evaluation

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Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dr. Susan Runner, FDA/CDRH, 9200 Corporate Blvd., HFZ-480, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Dr. Susan Runner at (301) 827-5283.

Additional Copies

World Wide Web/CDRH home page: http://www.fda.gov/cdrh, or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 2205 when prompted for the document shelf number.

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Guidance for the Preparation of Premarket Notifications for OTC Denture Cushions or Pads, OTC Denture Reliners, OTC Denture Repair Kits, and Partially Fabricated Denture Kits

1.0 INTRODUCTION

The purpose of this document is to provide guidance to the manufacturers of OTC denture cushions or pads, OTC denture reliners, OTC denture repair kits, and partially fabricated denture kits on the information desired for a more thorough and consistent preparation of a Premarket Notification submission (510(k)).

The development of this document is based on information recommended for a complete and adequate review by the Dental Devices Branch. The use of this document for the preparation of a 510(k) for OTC denture cushions or pads, OTC denture reliners, OTC denture repair kits, and partially fabricated denture kits does not ensure FDA clearance of a device, and certain 510(k) submissions may require additional information not contained in this document. However, use of this document will help to ensure that the basic elements are present to conduct an evaluation of substantial equivalence.

This guidance is subject to revision depending upon development of new technological information and/or changes in regulatory requirements.

Standards

Medical device manufacturers may elect to rely upon recognized voluntary consensus standards during the design and testing phase of their devices. We recognize that consensus standards, such as ISO standards, undergo periodic review and are subject to revision. FDA has published a document entitled "Guidance on the Recognition and Use of Consensus Standards" which provides guidance to industry and FDA reviewers on the use of recognized consensus standards, including declaration of conformity to the standards, during the evaluation of premarket submissions (Federal Register/Volume 63, No. 37/Wednesday, February 25, 1998). This document and related lists of recognized standards are on the Internet at FDA's web site "**http://www.FDA.gov/cdrh**".

2.0 GENERAL INFORMATION

510(k) Summary or 510(k) Statement. In accordance with the Safe Medical Devices Act of 1990 and 21 CFR Part 807.87(h), the applicant must submit either: (1)A summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (i.e., a "510(k) summary"); or (2)a statement that safety and effectiveness information will be made available to interested persons upon request (i.e., a "510(k) statement"). The summary or statement should be clearly identified as a "510(k) summary" or a "510(k) statement".

Truthful and Accurate Statement. As required by 21 CFR Part 807.87(j), the applicant must also provide a Truthful and Accurate Statement that all data and information submitted in the premarket notification is truthful and accurate and that no material fact has been omitted.

Indications for Use Form. On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indications for Use" the indications(s) for use of their device and the device trade name.

The New 510(k) Paradigm

On March 19, 1998, new procedures for the submission of 510(k)'s became effective. These procedures are collectively called the "New 510(k) Paradigm." More information on the New 510(k) Paradigm is available at the following Website address:

http://www.fda.gov/cdrh/ode/parad510.pdf

3.0 DEVICE DEFINITIONS

An **OTC denture cushion or pad** is a prefabricated or noncustom made disposable device that is intended to improve the fit of a loose or uncomfortable denture, and is available for purchase over the counter. The device is made of wax-impregnated cotton cloth that the patient applies to the base or inner surface of a denture before inserting the denture into the mouth and discarded following one day's use (class I); or the device is made of a material other than wax-impregnated cotton cloth or is not intended to be discarded following one day's use (class III). See 21 CFR Part 872.3540.

An **OTC denture reliner** is a device consisting of a material such as a plastic resin that is intended to be applied as a permanent coating or lining on the denture base. The device is intended to replace a worn denture lining and is available for purchase over the counter. See 21 CFR Part 872.3560.

An **OTC denture repair kit** is a device consisting of a material such a resin monomer system of powder and liquid adhesives, intended to be applied permanently to a denture to repair cracks or breaks. The device is available for purchase over the counter. See 21 CFR Part 872.3570.

A **partially fabricated denture kit** is a device composed of connected preformed teeth that is intended for use in the construction of a denture. A denture base is constructed using the patient's mouth as a mold, by partially polymerizing the resin denture base materials while the materials are in contact with the oral tissues. After the denture base is constructed, the connected preformed teeth are chemically bonded to the base. This is a prescription device and is not available over the counter. See 21 CFR Part 872.3600.

4.0 PRODUCT DESCRIPTION

- State the classification name and the trade name of the device.
- Submit a detailed description of your product and its indication(s) for use.
- Clearly specify whether a single paste or two paste (base/catalyst) system is employed, and all components of the system or kit.
- Provide a descriptive or table comparison of the similarities and differences to a legally marketed predicate device in terms of intended use, chemical composition, physical characteristics, mechanical properties, safety and effectiveness.

5.0 CHEMICAL IDENTITY

- Provide the complete material formulation, identifying the individual components by percentage, to a sum of 100%.
    - Note the function of each chemical component.
    - Do not omit any chemical component nor provide generalizations under a vague description such as "polymer compound."

- Provide the specific chemical name, and not a proprietary or trade name, or abbreviated chemical name.

- Disclose all the pigments or other colorants used in the formulation.

- Include the material safety data sheet (MSDS) for each chemical component, a diagram of the chemical structure and the molecular formula of the finished material, and the Chemical Abstracts Service (CAS) number if available.

6.0 PHYSICAL AND MECHANICAL PROPERTIES

The denture base material should be compared to the predicate material in terms of:

- Color Stability (Clear, Translucent, etc.)
- Hardness (Knoop, HK)
- Linear Shrinkage (%)
- Peak Temperature of Polymerization (°C)
- Porosity (bubbles or voids visible at 40 cm)
- Solubility (mg/cm^2)
- Strength (Transverse Deflection, mm)
- Water Absorption (mg/cm^2)

If the physical properties of the denture base material conform to a consensus standard for performance testing, the specific standard should be referenced as follows:

Denture base material	*ANSI/ADA Specification No.*
Denture Base Polymers	#12
Denture Cold-Curing Repair Resins	#13
Denture Base Temporary Relining Resins	#17

A summary should be provided of the methodology and results of all bench testing that has been conducted. The quantitative test results for your materials testing should compared to those of predicate impression materials.

7.0 BIOCOMPATIBILITY TESTING

Biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The device materials should not, either directly or through the release of their material constituents: (1)Produce significant adverse local or systemic effects; (2)be carcinogenic; or (3)produce adverse reproductive and developmental effects. Therefore, evaluation of any new device intended for human use requires data from systematic testing to ensure that the benefits provided by the final product will exceed any potential risks produced by device materials.

The ISO standard, ISO-10993, Part 1 uses an approach to test selection that is very similar to the Tripartite Guidance used in the past by FDA. It also uses a tabular format (matrix) for laying out the test requirements based on the various factors discussed above. The matrix consists of two tables, "Initial Evaluation Tests for Consideration" and "Supplementary Evaluation Tests for Consideration." To harmonize biological response testing with the requirements of other countries, FDA has recognized the ISO standard. Reviewers in the Office of Device Evaluation will accept data developed according to ISO-10993, Part 1, with the matrix as modified and presented in Blue Book Memorandum #G95-1 entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing."

Manufacturers are advised to begin discussions with the Dental Devices Branch prior to the initiation of expensive, long-term testing of any new device materials to ensure that the proper testing will be conducted, and to avoid unnecessary tests.

Biocompatibility testing is indicated when the product contains a "new" or nonconventional chemical component, and for which the safety or effectiveness of the resulting formulation is in question. A material may be considered new based upon several factors, such as methods of manufacture, sterilization, duration of body exposure, etc. The biocompatibility tests should be performed on the finished product, i.e., in a form as close as possible to what the patient will be exposed to.

The following tests have been identified as necessary for the evaluation of substantial equivalence in such a case. This is a list of the minimum testing which should be addressed in a regulatory submission.

-In Vitro Cytotoxicity
-Ames Test for Mutagenicity
-Mucus Membrane Irritation (hamster's pouch)
-Sensitization Test in Guinea Pigs, and
-Carcinogenicity (if tumorigenic potential has not been previously documented)

For details on how to conduct these tests, refer to an appropriate international standard such as: American National Standard/American Dental Association Document No. 41 for Recommended Standard Practices for Biological Evaluation of Dental Materials,1982; or ISO/TR: 1984(E), Biological Evaluation of Dental Materials, 1984.

8.0 LABELING

It is important to the consumer that the labeling for the OTC denture cushions or pads, OTC denture reliners, and OTC denture repair kits bear clear, accurate, and complete information for use concerning any relevant indications, method of preparation, hazards, contraindications, and precautions in their use.

As set forth in 21 CFR Part 801.405, recommended warning statements include:

> Denture Reliners, Pads, and Cushions:
> *Warning*—For temporary use only. Long term use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For Use Only Until A Dentist Can Be Seen.
>
> Denture Repair Kits:
> *Warning*—For emergency repairs only. Long term use of home-repaired dentures may cause faster bone loss, continuing irritation, sores, and tumors. This kit for emergency use only. See Dentist Without Delay.

Include in the 510(k) submission for OTC denture cushions or pads, OTC denture reliners, OTC denture repair kits, and partially fabricated denture kits, the proposed package labels and labeling, including any promotion and advertising information. Labeling refers to the package label plus other written, printed, or graphic material that accompanies the device or that is placed on either the device or any of its wrappers or containers. Advertising may be considered labeling, especially if it accompanies the device. The labeling must bear adequate directions for use and any warnings needed to ensure the safe use of the device. See sections 201(k) and (m) and 502(f)(1) and (2) of the Federal Food, Drug, and Cosmetic Act.

If you wish specific advice on the applicability to your device of the FDA labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Additionally, note the regulation titled "Misbranding by reference to premarket notification" (21 CFR Part 807.97).

9.0 CONTACT

Questions regarding this guidance should be addressed to:

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General information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet web site: **http://www.fda.gov/cdrh/dsma/dsmamain.html**.