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

Document issued on: April 22, 2003

For questions regarding this document contact Michael Adjodha at 301-796-6276 or by email: **michael.adjodha@fda.hhs.gov (mailto:michael.adjodha@fda.hhs.gov)**.

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

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

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to **CDRH-Guidance@fda.hhs.gov (mailto:CDRH-Guidance@fda.hhs.gov)** to receive a copy of the guidance. Please use the document number (1203) to identify the guidance you are requesting.

Guidance for Industry and FDA Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations

Background

FDA is exempting optical impression systems for the computer assisted design and manufacturing (CAD/CAM) of dental restorations 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 optical impression systems for CAD/CAM of dental restorations may comply with the requirement of Class II Special Controls. Designation of this guidance document as a special control means that manufacturers of optical impression systems for CAD/CAM of dental restorations 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 a final rule exempting the device, manufacturers of optical impression systems for CAD/CAM of dental restorations will need to address the issues covered in this special control guidance. The firm must show that its device addresses the issues of safety and effectiveness identified in this guidance, either by meeting the recommendations of this guidance

or by some other means that 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.

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 comply with 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 "**A Suggested Approach to Resolving Least Burdensome Issues (/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm)**" document.

Scope

An optical impression system for CAD/CAM of dental restorations is a medical device that is used to record the topographical features of teeth, impression materials, or stone models. The device is called a "system" because it typically consists of three integrated functions or modules: a scanning module - consisting of a camera, infrared scanner, or equivalent type of sensor; a central processing module - consisting of computer hardware and software; and a manufacturing module - consisting of a computer-controlled milling machine. The central processing module uses the image captured by the scanning module to mill a restoration in the manufacturing module. The restorations are fabricated from ceramic, resin, or metal blocks, which are regulated elsewhere as Class II devices.[2]

Though marketed as a whole system, not all modules of the optical impression system are subject to premarket notification. In FDA correspondence dated December 5, 1988,[3] the Agency determined that, as a fabrication tool, the manufacturing module of optical impression systems did not require premarket notification, while maintaining that the scanning and central processing modules were subject to premarket notification. Since that time, the agency has regulated the device as a class II device, either as an accessory to impression materials[4] or to the material being milled.

For clarity, following the effective date of the final rule in the Federal Register, FDA is designating these devices as "optical impression systems for computer assisted design and manufacturing (CAD/CAM)" and placing them in a new section, 21 CFR 872.3661. The devices will continue to be regulated as class II devices, but are exempt from premarket notification requirements.

FDA defines optical impression systems for CAD/CAM of dental restorations as follows:

> An optical impression system for CAD/CAM of dental restorations is a device used to record the topographical characteristics of teeth, dental impressions, or stone models by analog or digital methods for use in the computer aided design and manufacturing of dental restorative prosthetic devices. Such systems may consist of a camera, scanner, or equivalent type of sensor and a computer with software.

The scope of this guidance does not apply to impression materials or the material milled, e.g., ceramic, resin, or metal. These materials are regulated elsewhere in Part 872.

Risks to Health

FDA has identified the following risks to health associated with the use of the optical impression systems for CAD/CAM of dental restorations in the table below. FDA recommends the following measures to mitigate the identified risks in this guidance, as shown in the table below.

Identified risks	**Recommended mitigation measures**
Dimensional Inaccuracy	1. Software Validation* 5. Labeling
Adverse Tissue Reaction	2. Biocompatibility
Electrical Hazards	3. Electrical Safety
Electromagnetic Interference	4. Electromagnetic Compatibility
Cross-Contamination	5. Labeling

*The subheadings correspond to mitigation measures in the following section.

Recommended Mitigation Measures

FDA believes that conformance with this guidance document, when combined with the general controls of the Act, will provide reasonable assurance of the safety and effectiveness of the optical impression systems for CAD/CAM of dental restorations. We recommend that you (the manufacturer) evaluate your device as described below and, where appropriate, document the results in your design history file as a part of the Quality Systems Requirements (21 CFR 820.20).

1. Software Validation

We recommend that you validate your imaging software in accordance with the general principles outlined in the FDA guidance, **General Principles of Software Validation; Final Guidance for Industry and FDA Staff; January 11, 2002**

(/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085371.pdf) in order to assure that your optical impression system is dimensionally accurate, i.e., the detail reproduction of the final product meets user needs.

2. Biocompatibility

We recommend that you insure the biocompatibility of the patient-contacting parts of your device by complying with the tests in the following standard for a limited contact, surface device on mucosal membrane:

- International Standard Organization (ISO) standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

3. Electrical Safety

We recommend that you insure the electrical safety of your device by complying with the following standard

- International Electrotechnical Commission (IEC) 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety

4. Electromagnetic Compatibility

We recommend that you insure the electromagnetic compatibility (EMC) of your device by complying with the following standard:

- IEC 60601-1- 2 Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001).

5. Labeling[5]
As a prescription device, under **21 CFR 801.109 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=801.109)**, the device is exempt from having adequate directions for lay use. Nevertheless, we recommend that you provide sufficient directions for use, including instructions on the appropriate infection control procedures to follow between each patient use of your device. We recommend that you evaluate your infection control procedures in accordance with the Centers for Disease Control and Prevention document "**Recommended Infection-Control Practices for Dentistry, 1993. (http://www.cdc.gov/mmwr/preview/mmwrhtml/00021095.htm)**"

Limitations of Exemption from Premarket Notification

FDA's decision to exempt a Class II device from the requirement of premarket notification 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 premarket notification 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
- is an in vitro device that is intended for any of the uses specified in 872.9.

If any of these limitations apply, your device is not exempt and you must submit a premarket notification.

---

[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.
(**back**)

[2] These materials are regulated separately under Parts 872.6660, 872.3690, 872.3710, and 872.3060 and are not subject to this guidance. (**back**)

[3] FDA correspondence to Dentsply, International, December 5, 1988. (**back**)

[4] Regulated under Part 872.3660 (**back**)

[5] Final labeling must comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. (**back**)

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)