Guidance for Industry and FDA Staff

Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions

Document issued on: October 26, 2005

This guidance supersedes "Guidance for Industry and FDA Staff Dental Composites -Premarket Notification" issued November 27, 1998

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

Contains Nonbinding Recommendations

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 the exact title of this guidance document. 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. Introduction

FDA has developed this guidance document to assist industry in preparing premarket notification submissions (510(k)s) for composite restorative resins used in dentistry. The term composite denotes that these resins are generally composed of a heterogenous mixture of materials.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe should 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 "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at http://www.fda.gov/cdrh/modact/leastburdensome.html.

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.

2. Background

A manufacturer who intends to market a device of this generic type should conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the act), including the premarket notification requirements described in 21 CFR 807 Subpart E, and obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.81 and 807.87.)

This guidance document identifies the classification regulations and product codes for dental composite resin devices (refer to **Section 4**). In addition, other sections of this guidance document provide additional information to manufacturers on addressing risks related to these devices in premarket notifications (510(k)s).

This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87 and **"How to Prepare a 510(k) Submission**" on FDA Device Advice at http://www.fda.gov/cdrh/devadvice/314.html.

Under "**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**," http://www.fda.gov/cdrh/ode/parad510.html, a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once FDA has issued a guidance document addressing that device. Manufacturers considering certain modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this guidance document was used during the device development and testing and should briefly describe the methods or tests used. We recommend that you also include a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section

suggests information to fulfill some of the requirements of 21 CFR 807.87, as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this guidance document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to **Section 9** for specific information that we recommend you include in labeling.)

Summary report

We recommend that the summary report contain a:

Description of the device and its intended use
We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Refer to **Section 5** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.[1]

Description of device design
We recommend that you include a brief description of the device design requirements.

Identification of the risk analysis method
We recommend that you identify the risk analysis method(s) you used to assess the risk profile, in general, as well as the specific device's design and the results of this analysis. (Refer to **Section 6** for the risks to health generally associated with the use of this device that FDA has identified.)

Discussion of the device characteristics
We recommend that you discuss the device characteristics that address the risks identified in this guidance document, as well as any additional risks identified in your risk analysis.

[1] Refer to http://www.fda.gov/cdrh/ode/indicate.html for the recommended format.

Description of the performance aspects
We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 7** and **8** of this guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.[2] (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

Reliance on standards
If you choose to rely on a recognized standard for any part of the device design or testing, you may include either a:

- statement that testing will be conducted and meet specified acceptance criteria before the device is marketed; or
- declaration of conformity to the standard.[3]

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/1131.html.

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need to assess the

[2] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[3] See **Required Elements for a Declaration of Conformity to a Recognized Standard** (Screening Checklist for All Premarket Notification [510(K)] Submissions), http://www.fda.gov/cdrh/ode/reqrecstand.html.

adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering certain modifications to their own cleared devices should consider submitting Special 510(k)s.

4. Scope

The scope of this guidance is limited to the devices in the table below.

Table 1: Devices within the scope of this guidance document:

Device	Classification	Class	Product Code
Tooth Shade Resin Material	21 CFR 872.3690	II	EBF
Pit and Fissure Sealant and Conditioner	21 CFR 872.3765	II	EBC

These devices are intended to fill and restore small to large defects or carious lesions in teeth. These devices may be supplied as two-part base and catalyst systems, cured by chemical activation, or one-part systems, cured by photo initiation, with or without chemical activation.

The scope of this guidance does not include the resin materials in the table below, which are intended for other uses; e.g., cementing, coating, fixation, and temporary restoration.

Table 2: Devices not within the scope of this guidance document

Device	Classification
Resin Tooth Bonding Agent	21 CFR 872.3200
Dental Cement	21 CFR 872.3275
Coating Material for Resin Fillings	21 CFR 872.3310
Bracket Adhesive Resin and Tooth Conditioner	21 CFR 872.3750
Temporary Crown and Bridge Resin	21 CFR 872.3770

5. Device Description

We recommend that you identify your device by regulation and product code identified in **Section 4**. and include a description of:

- the principle of operation; i.e., how the device achieves its intended purpose
- how the device will be marketed, including all accessories.

We recommend that you compare your device with a legally marketed predicate device and that you provide information to show how the new device is both similar to and different from the predicate device. Side by side comparisons, whenever possible, are desirable, for example, using a tabular format as shown below. We also recommend that you describe how any differences may affect the comparative safety and effectiveness of the new device.

Table 3: Comparison of New and Predicate Devices

Descriptive Information	New Device	Predicate Device
Intended Use – including the indication for use		
Composition of Materials – the chemical composition of device		
Physical Properties – e.g., compressive strength, flexural strength, particle size range, depth of cure		
FDA-Recognized Standards* – those you have followed; e.g., standards on material characterization and biocompatibility		

* For the list of FDA-Recognized Standards, see www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of dental composite resin devices addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. You should also conduct a risk analysis, before submitting your 510(k), to identify any other risks specific to your device. The 510(k) should describe the risk analysis method used and include the results of this analysis. If you elect to use an alternative approach to address a particular risk identified in this document or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address

that risk.

Table 4: Device Risks and Recommended Mitigation Measures

Identified Risks	Recommended Mitigation Measures
Mechanical Failure	Section 7. Composition and Physical Property Specifications
Toxicity and Adverse Tissue Reaction	Section 8. Biocompatibility
Improper Use	Section 9. Labeling

7. Composition and Physical Property Specifications

We recommend that you evaluate your dental composite resin device using the relevant FDA-recognized standard listed below or equivalent method:

ISO 4049:2000(E), Dentistry—Polymer-based filling, restorative and luting materials

A. Chemical Composition

We recommend that you include a description of the complete chemical composition, totalling 100 percent by mass, including all additives, fillers, and colorants, and the Chemical Abstracts Service[4] (CAS®) registry number of all components. All colorants should be identified by either the CAS® number or Color Index Number.

B. Physical Properties

We recommend that you describe the following physical properties:

- compressive strength (MPa)
- flexural strength (MPa)
- elastic modulus (GPa)
- intensity (mW/cm^2) for curing (for photoinitiated resins)
- wavelength (nm) for curing (for photoinitiated resins)
- depth of cure (mm) (for photoinitiated resins)

[4] http://www.cas.org/EO/regsys.html

- filler particle size distribution (µ)
- surface hardness (KHN)
- radio-opacity (mm of Al)
- water sorption (µg/mm^3)
- solubility (µg/mm^3)
- release profile (µg/mm^3) (If the device contains a releasable agent such as fluoride or nitrate ions, plot of the cumulative concentration of ions released by a representative sample versus time for each day over the first 7 days in distilled water at 37 °C.)
- working time (sec)
- curing time (sec) (for photoinitiated resins)
- setting time (min).

C. Performance in Vivo

In accordance with the least burdensome provisions of the act, the Agency will rely upon well-designed bench and/or animal testing rather than requiring clinical studies for new devices, unless there is a justification for asking for clinical information to support a determination of substantial equivalence. While in general, clinical studies may not be needed for most dental composite resin devices, FDA may recommend that you collect clinical data for a dental composite resin device for any of the following:

- indications for use dissimilar from legally marketed dental composite resin devices of the same type; e.g., indications associated with bone remineralization, caries prevention, or other therapeutic benefits

- designs dissimilar from designs previously cleared under a premarket notification; e.g., novel polymer systems

- new technology, i.e., technology different from that used in legally marketed dental composite resin devices; e.g., novel setting mechanism or placement technique.

If a clinical study is needed to demonstrate substantial equivalence; that is, conducted prior to obtaining 510(k) clearance of the device, the study must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812. In general, FDA believes that dental composite resin devices addressed by this guidance document are nonsignificant risk devices, and therefore the study is subject to the abbreviated requirements

of 21 CFR 812.2(b).[5] In addition to the requirements of section 21 CFR 812.2(b), sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale.

If you conduct animal testing, we recommend that your study include:

- an animal model representative of the indications for use and involving the same anatomical sites as the indications for your device
- the use of skeletally mature animals
- the predicate device as the positive control
- radiographs, photographs, or other clinical or histological methods to assess the performance of the restoration.

The Dental Devices Branch is available to answer your questions about pre-clinical testing and clinical study protocols.

8. Biocompatibility

We recommend that you conduct biocompatibility testing for your dental composite resin device as described in **ISO 7405:1997(E), Dentistry - Preclinical evaluation of biocompatibility of medical devices used in dentistry—Test methods for dental materials** or equivalent method.

If the composition of your dental composite resin device, including all colorants, has already been demonstrated as biocompatible in the same indication and type of tissue contact in a predicate device or in the literature, in lieu of biocompatibility testing, you may identify the predicate or the references to support the biocompatibility of your device.

9. Labeling

The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR Part 801.[6]

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[5] http://www.fda.gov/oc/ohrt/irbs/devices.html#risk.

[6] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

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We recommend that the labeling of your dental composite resin device be written in sufficient detail to enable a practitioner to determine the physical properties of the device. Labeling should include:

- compressive strength (MPa)
- flexural strength (MPa)
- light intensity (mW/cm^2) for curing
- wavelength (nm) for curing
- depth of cure (mm)
- working time (sec)
- curing time (sec) (for photoinitiated resins)
- setting time (min)
- any other properties relevant to your device.