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Draft – Not for Implementation

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

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on July 12, 2024.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices/DHT1B: Division of Dental and ENT Devices at 301-796-5620.

When final, this guidance will supersede "Dental Composite Resin Devices – Premarket Notification [510(k)] Submissions" issued October 26, 2005.

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CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
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Preface

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

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This draft guidance document provides draft recommendations for 510(k) submissions for dental composite resins used in dentistry. The device is intended to fill and restore defects or carious lesions in teeth. The device may be supplied as a two-part base and catalyst system that is self-cured or a one-part system that is cured via photoinitiation. The recommendations reflect current review practices and are intended to promote consistency and facilitate efficient review of these submissions.

This draft guidance, when final, will supersede the guidance "Dental Composite Resin Devices – Premarket Notification [510(k)] Submissions" issued October 26, 2005. This document supplements other FDA documents regarding the specific content requirements and recommendations of a 510(k) submission. You should also refer to 21 CFR 807.87 and FDA's guidance, "Electronic Submission Template for Medical Device 510(k) Submissions."

For the current edition of the FDA-recognized consensus standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database. If submitting a Declaration of Conformity to a recognized standard, we recommend you include the appropriate supporting documentation. For more information regarding use of consensus standards in regulatory submissions, refer to the FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."

In general, FDA's guidance documents 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.

II. Scope

The scope of this document is limited to dental composite resins regulated under 21 CFR 872.3690 and 21 CFR 872.3765 and with product codes listed in the table below:

Table 1: Applicable Product Codes

Product Code	Product Code Name	Regulation Number
EBF	Tooth Shade Resin Material	21 CFR 872.3690
EBC	Pit and Fissure Sealant and Conditioner	21 CFR 872.3765

The scope of this guidance does not include the resin restoratives intended for other uses, such as cementing, coating, fixation, and temporary restoration (i.e., devices classified in 21 CFR 872.3200; 21 CFR 872.3275; 21 CFR 872.3310; 21 CFR 872.3750; and 21 CFR 872.3770). This guidance applies to dental composite resins that are combination products; however, it does not address specific considerations unique to combination products.

III. Premarket Submission Recommendations

A. Device Description

We recommend that you identify your device by the applicable regulation number and product code indicated in Section II above and include the information described below.

We recommend you provide a complete description of all formulations, components, and accessories that are intended to be marketed with the device including:

- A description of the device's principle of operation for achieving its intended purpose, e.g., a description of the curing chemistry and any substances that may be eluted from the device;
- A complete chemical composition for each formulation of the device, including all polymers, monomers, initiators, curing agents, stabilizers, plasticizers, eluting agents, filler, colorants, and other additives, and a complete quantification of these substances by percent mass, with the sum totaling to 100 percent by mass (*see* Section III.F.(1));

- Descriptions of any accessories that are packaged with the device, e.g., dispensers, mixing tips, and mixing pads;
- Labeled images and/or illustrations of all components or accessories that are included as part of the packaged device; and
- Identification of the 510(k) clearance status (including the 510(k) number, if available) of any accessory devices that are to be used or packaged with the device, if applicable.

B. Predicate Comparison

For devices reviewed under the 510(k) process, manufacturers must compare their new device to a similar legally marketed predicate device to support its substantial equivalence (section 513(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); 21 CFR 807.87(f)). This comparison should provide information to show how your device is similar to and different from the predicate. Side by side comparisons, whenever possible, are desirable. See below for an example of how this information may be organized. This table is not intended to represent an exhaustive list of comparative parameters; ensure you provide all relevant device descriptive and performance characteristics.

Table 2: Sample predicate comparison table to outline differences and similarities between the subject and predicate devices

Description	Subject Device	Predicate Device (Kxxxxxx)
Indications for Use		
Principle of operation		
Mechanism of action		
Materials – the chemical composition of patient-contacting portions of the device		
Compressive strength		
Flexural strength		
Depth of cure		
Hardness		
Water absorption		
Water solubility		
Other relevant characteristics…		

C. Labeling

The premarket notification must include proposed labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Proposed labels and labeling, sufficient to describe the dental composite resin device, its intended use, and the directions for use must be provided.

As prescription devices, dental composite resins are exempt from the requirement to have adequate directions for lay use required under section 502(f)(1) of the FD&C Act as long as the conditions in 21 CFR 801.109 are met. For instance, to be so exempt, labeling that furnishes information for use of the prescription device must, among other things, contain adequate information for such use, including indications, effects, routes, methods, and frequency, and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended (21 CFR 801.109(d)).

We recommend that the instructions for use include the following information, when applicable:

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

D. Shelf Life

Significance: Shelf life testing is conducted to support the proposed expiration date through evaluation of any changes to device performance or functionality.

Recommendation: With respect to evaluating the effects of aging on device performance or functionality, shelf life studies should evaluate the critical device properties to ensure it will perform adequately and consistently during the entire proposed shelf life. To evaluate device functionality, we recommend that you assess each of the bench tests described in Section III.F and repeat all tests that evaluate design components or characteristics that are potentially affected by aging using aged devices.

We recommend that you provide a summary of the test methods used for your shelf life testing, results and the conclusions drawn from your results. If you use devices subject to accelerated aging for shelf life testing, we recommend that you specify the way in which the device was aged and provide a rationale to explain how the results of shelf life testing based on accelerated aging are representative of the results if the device were aged in real time. We recommend that you age your devices as per the currently FDA recognized version of ASTM F1980 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* and specify the environmental

parameters established to attain the expiration date. Since dental composite resins are composed of polymeric materials, you should conduct testing on real-time aged samples to confirm the results of the accelerated aging study. This testing should be conducted in parallel with 510(k) review and clearance with results documented to file in the design history file[1] (i.e., complete test reports do not need to be submitted to FDA).

E. Biocompatibility

Significance: Dental composite resins contain patient-contacting materials, which, when used for their intended purpose, (i.e., contact type and duration), may induce a harmful biological response.

Recommendation: You should determine the biocompatibility of all patient-contacting materials present in your device. If your device is identical in chemical composition, manufacturing and processing methods to dental composite resins with a history of safe use, you may reference previous testing experience or the literature, if appropriate. For some device materials, it may be appropriate to provide a reference to either a recognized consensus standard, or to a Letter of Authorization (LOA) for a device Master File (MAF). You should refer to the following FDA webpage for additional information on using device MAFs: https://www.fda.gov/medical-devices/premarket-approval-pma/master-files.

If you are unable to identify a legally marketed predicate device with the same nature of contact and contact duration that uses the same materials and manufacturing process as used in your device, we recommend you conduct and provide a biocompatibility evaluation as described in ISO 7405 *Dentistry - Evaluation of biocompatibility of medical devices used in dentistry* for the endpoints outlined below. Per FDA's guidance, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'," when FDA-recognized consensus standards exist for a particular device type, the biocompatibility recommendations in the device-specific consensus standard should be used instead of the recommendations outlined in ISO 10993-1. The biocompatibility evaluation should explain the relationship between the identified biocompatibility risks, the information available to mitigate the identified risks, and any knowledge gaps that remain. You should then identify any biocompatibility testing or other evaluations that were conducted to mitigate any remaining risks. We recommend that you consider the recommendations in this guidance or the

[1] On February 2, 2024, FDA issued a final rule amending the device quality system (QS) regulation, 21 CFR part 820, to align more closely with international consensus standards for devices. FDA also made conforming amendments to 21 CFR part 4 (89 FR 7496). This final rule will take effect on February 2, 2026. Once in effect, this rule will amend the majority of the current requirements in part 820 and incorporate by reference the 2016 edition of the International Organization for Standardization (ISO) 13485, Medical devices – Quality management systems – Requirements for regulatory purposes, in part 820. As stated in the final rule, the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the current part 820, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the FD&C Act. When the final rule takes effect, FDA will also update the references to provisions in 21 CFR part 820 in this guidance to be consistent with that rule.

standard, which identifies the types of biocompatibility assessments that should be considered and recommendations regarding how to conduct related tests.

Per ISO 7405 *Dentistry - Evaluation of biocompatibility of medical devices used in dentistry* or ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and Attachment A of FDA's guidance on ISO-10993-1, dental composite resins are external communicating devices in contact with tissue/bone/dentin for a permanent contact duration.

The following endpoints should be addressed in your biocompatibility evaluation:

- cytotoxicity;
- sensitization;
- irritation or intracutaneous reactivity;
- acute systemic toxicity;
- subacute/subchronic toxicity; and
- genotoxicity.

F. Non-Clinical Performance Testing

Non-clinical performance testing is recommended for dental composite resin devices because descriptive characteristics alone are insufficient to support a substantial equivalence determination. FDA has recognized a number of voluntary consensus standards[2] with test methods and predefined acceptance criteria for this device type. As such, a Declaration of Conformity to these standards can be used to help demonstrate substantial equivalence and can reduce the amount of supporting data and information that are submitted to FDA. For more information regarding use of consensus standards and/or a Declaration of Conformity in regulatory submissions, refer to the FDA's guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices." For non-clinical performance tests that do not rely on an FDA-recognized consensus standard, we recommend that you provide full test reports, with a summary of the findings, for each test conducted. You should also provide an explanation of how the data generated from the test supports a finding of substantial equivalence.

For information on the recommended content and format of test reports for the testing described in this section, refer to FDA's guidance, "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions."

[2] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

(1) Material Characterization

Significance: Material characterization is a complete description of all chemical substances used in the dental composite resin device. Incomplete material characterization can result in increased risk to patients as a result of unintentional exposure to plasticizers, stabilizers, color additives,[3] and other additives whose safety profile has not been adequately evaluated. A complete material characterization helps to provide assurance that the risks introduced by the formulation of the device are adequately understood and addressed.

Recommendation: We recommend that you identify the complete chemical composition of all chemical substances in your device, including all polymers, monomers, initiators, curing agents, stabilizers, plasticizers, eluting agents, filler, colorants, and other additives, and quantify these substances by percent mass, with the sum totaling to 100 percent by mass. All substances should be identified by their Chemical Abstracts Service (CAS)[4] Registry Number®, if available. Color additives may be identified by reference to those in 21 CFR Parts 73 and 74, by CAS Registry Number®, or Colour Index™ number, if available.

If your device contains fluoride or other eluting agents, such as calcium, phosphorus, or nitrate ions, we recommend that you quantify the release profile of these substances over time. We recommend that you provide a plot of the cumulative release concentration (µg ion/volume of sample (mm^3)) of ions released from a representative sample of the device versus time (days) in 10 ml of distilled water at 37 °C each day for a total of 7 days. The cumulative release concentration is the total concentration that sums each day's concentration with all previous measurements. During this test, the water should be replaced each day.

(2) Physical and Mechanical Properties

Significance: Physical and mechanical properties are a measure of the material properties of a dental composite resin device. Inadequate physical and mechanical properties can result in premature failure of the device and the need for revisional dental treatment. Physical and mechanical property testing provides assurance that the device has sufficient properties for its intended use.

Recommendation: We recommend that you evaluate the physical and mechanical properties of your dental composite resin device using test methods that conform to the currently FDA-recognized versions of the following standards:

- ISO 4049 *Dentistry — Polymer-based restorative materials*
- ISO 6874 *Dentistry — Polymer-based pit and fissure sealants*
- ISO 9917-2 *Dentistry – Water-based cements – Part 2: Resin-modified cements*

[3] For more information on color additives in medical devices, refer to the FDA webpage: https://www.fda.gov/industry/color-additives-specific-products/medical-devices

[4] Refer to Chemical Abstracts Service (CAS) website for additional information (http://www.cas.org)

We recommend that you provide results of the following tests to assure that your device has sufficient strength, stiffness, hardness, and water insolubility for its intended use:

- compressive strength (MPa);
- flexural strength (MPa);
- elastic modulus (GPa);
- surface hardness (KHN);
- water absorption ($\mu g/mm^3$); and
- water solubility ($\mu g/mm^3$).

If you include any performance statements that your device is a "hybrid" (i.e., includes macro and micro filler particle sizes) or "nanofilled" composite resin, we also recommend that you provide the filler particle size distribution (μ), i.e., the size range of filler particle sizes included in your device.

(3) Energy for Curing Photoinitiated Resins

Significance: The amount of energy needed to cure a photoinitiated dental composite resin varies with the type of initiator used in the device, the shade, filler type, size, loading, and thickness of the device. Inadequate energy delivery from external sources, such as a dental curing light, can cause incomplete curing and premature failure of a dental composite resin device. Characterizing the energy needed to cure a photoinitiated dental composite resin device will facilitate the selection of an appropriate dental curing light and provides assurance that the dental composite resin device will have the sufficient properties for its intended use.

Recommendation: For photoinitiated dental composite resins, we recommend that you provide the results of the following performance tests using the methods from the currently FDA-recognized version of ISO 4049 to characterize the energy needed to cure your dental composite resin device. Tests should be performed on a representative or "universal" shade, unless otherwise specified:

- light intensity (radiant exitance) (mW/cm^2) for curing;
- wavelength (nm) for curing;
- curing times (sec) for all shades; and
- depth of cure (mm) for normal mode at 10 seconds.

(4) Working and Setting Times for Self-Curing Resins

Significance: Self-curing dental composite resins are mixed and activated at the time of treatment. The dental practitioner has limited time (i.e., working time) in which to prepare the restoration before it begins to harden. Once placed, the restoration may not be fully functional until the resin is allowed to set (i.e., setting time). Accurate working and setting times are critical

to provide assurance that the dental practitioner will have sufficient time to place the restoration and that the patient may be advised to avoid chewing on the restored tooth until the restoration has fully cured.

Recommendation: For self-curing resins, we recommend that you provide the results of the following performance tests in order to characterize the working and setting times for your device:

- working time (sec); and
- setting time (min).

(5) Radiopacity

Significance: Radiopacity is the ability of a dental restorative composite to block the transmission of X-rays. This is important because it allows a dental practitioner to visualize the areas of a tooth that have been restored. Inadequate radiopacity can affect the ability of the practitioner to detect decay and assess the margins and the overall quality of the restoration. Radiopacity provides assurance that the dental composite resin restorations can be seen on a dental radiograph.

Recommendation: We recommend that you characterize the radiopacity of your device using the methods from the currently FDA-recognized version of ISO 4049.

G. Clinical Performance Testing

Significance: In some cases, non-clinical evaluation does not fully characterize all clinical experience, outcomes, and risks. In such cases, we recommend that you conduct clinical studies to evaluate device safety and effectiveness for new and modified dental composite resin devices.

Recommendation: Clinical evidence is generally unnecessary for most dental composite resin devices; however, such testing may be requested in situations such as the following:

- any statements about device performance, such as longevity, tooth remineralization, reduced decay or other enhanced clinical outcomes.

We will consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. If a clinical investigation is conducted involving one or more subjects to demonstrate substantial equivalence of a device, the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812 applies unless the investigation is excepted from the IDE requirements (see 21 CFR 812.3(a) and (c)). Generally, we believe dental composite resin devices addressed by this guidance document are non-significant risk devices; therefore, the study would be subject to the abbreviated requirements of 21 CFR 812.2(b). See the FDA Guidance titled, "Significant Risk and Nonsignificant Risk Medical Device Studies." In addition to the requirements of Section 21 CFR 812, sponsors of such trials in the U.S. must generally comply with the regulations governing institutional review boards (21 CFR Part 56) and the

protection of human subjects (21 CFR Part 50), including informed consent (21 CFR Part 50, subpart B).

When data from clinical investigations conducted outside the U.S. are submitted to FDA for these devices, the requirements of 21 CFR 812.28 may apply.[5] 21 CFR 812.28(a) outlines the conditions for FDA acceptance of data from clinical investigations conducted outside the United States to support an IDE or a premarket submission. For more information, see the FDA guidance "Acceptance of Clinical Data to Support Medical Device Applications and Submissions: Frequently Asked Questions."

In some cases, "real-world data" (RWD) may be used to support labeling statements about enhanced clinical outcomes for a device for which 510(k) clearance has already been obtained. Whether the collection of RWD for a legally-marketed device requires an IDE depends on the particular facts of the situation. Specifically, if a cleared device is being used in the normal course of medical practice, an IDE would likely not be required. For additional information regarding this topic, refer to the FDA Guidance entitled "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices."

If you would like feedback on a clinical protocol or to discuss whether clinical data is recommended by FDA, you are encouraged to use the Q-submission process. For information on FDA's Q-submission process, see FDA's guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."

IV. Modifications

21 CFR 807.81(a)(3) provides that a device change or modification "that could significantly affect the safety or effectiveness of the device" or represents a "major change or modification in the intended use of the device" requires a new 510(k).[6] For additional details, see FDA guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device."

[5] This applies to data from clinical investigations that began on or after February 21, 2019 and are submitted to support a premarket submission, including IDEs, premarket approval applications (PMAs), and 510(k)s.

[6] Section 3308 of the Food and Drug Omnibus Reform Act of 2022 (FDORA), enacted as part of the Consolidated Appropriations Act, 2023, added section 515C "Predetermined Change Control Plans for Devices" to the FD&C Act (Pub. L. No. 117-328). Section 515C provides FDA with express authority to approve or clear PCCPs for devices requiring premarket approval or premarket notification. For example, section 515C provides that supplemental applications (section 515C(a)) and new premarket notifications (section 515C(b)) are not required for a change to a device that would otherwise require a premarket approval supplement or new premarket notification if the change is consistent with a PCCP approved or cleared by FDA. Section 515C also provides that FDA may require that a PCCP include labeling for safe and effective use of a device as such device changes pursuant to such plan, notification requirements if the device does not function as intended pursuant to such plan, and performance requirements for changes made under the plan. If you are interested in proposing a PCCP in your marketing submission, we encourage you to submit a Pre-Submission to engage in further discussion with CDRH. See FDA's guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."