Contains Nonbinding Recommendations

Dental Cements – Performance Criteria for Safety and Performance Based Pathway

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Guidance for Industry and Food and Drug Administration Staff

GUIDANCE

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For questions about this document, contact the OHT1/DHT1B: Division of Dental Devices at 301-796-5620.



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

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://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 [FDA-2024-D-4171]. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Dental Cements – Performance Criteria for Safety and Performance Based Pathway

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Draft Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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 guidance provides performance criteria for dental cements in support of the Safety and Performance Based Pathway. Under this framework, submitters planning to submit a 510(k) using the Safety and Performance Based Pathway for dental cements will have the option to use the performance criteria proposed in this guidance to support substantial equivalence, rather than a direct comparison of the performance of the subject device to that of a predicate device.

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, please refer to the FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."

This guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

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. Background

In September 2019, FDA issued a guidance to describe an optional pathway – the Safety and Performance Based Pathway – for certain, well understood device types, where a submitter could demonstrate that a new device meets FDA-identified performance criteria to demonstrate that the device is as safe and effective as a legally marketed device. In order to identify the specific set of performance criteria appropriate to satisfy a submitter's comparison to an appropriate predicate for a given device-type, FDA has determined that the performance criteria represent performance that meets the performance of one or more existing, legally marketed devices of that device type. Specifically, FDA relied on the experience and expertise of FDA staff, information in literature, and analyses of data available to FDA on legally marketed surgical sutures to determine the performance criteria and associated testing methods that could support a finding of substantial equivalence for surgical sutures as described in this guidance. FDA recognizes that in some cases, it may be more burdensome for a submitter to conduct testing against an appropriate predicate device to demonstrate equivalence for the necessary set of performance and technological characteristics than to demonstrate their device meets appropriate performance criteria established by FDA. Accordingly, we concluded that the optional device-specific Safety and Performance Based Pathway utilizing the performance criteria identified in this guidance provides a less burdensome policy consistent with the public health.

III. Scope/Device Description

The scope of this guidance document includes dental cements that are Class II devices classified under the regulations and product codes outlined in Table 1:

Table 1: Dental Cements in Scope of this Guidance

Regulation Name	Regulation	Product Code
Dental cement	21 CFR 872.3275	EMA
Resin tooth bonding agent	21 CFR 872.3200	KLE
Bracket adhesive resin and tooth conditioner	21 CFR 872.3750	DYH

The following are outside the scope of this guidance:

- Acid etching gels under 21 CFR 872.3200 (product code KLE)
- Zinc oxide-eugenol cements under 21 CFR 872.3275 (product code EMB)
- Dental Cement w/out Zinc-Oxide Eugenol as an Ulcer Covering for Pain Relief under 21 CFR 872.3275 (product code MZW)
- Tooth Shade Resin Material under 21 CFR 872.3690 (product codes EBF and OFW)
- Coating Material for Resin Fillings under 21 CFR 872.3310 (product code EBD)
- Pit and Fissure Sealant and Conditioners under 21 CFR 872.3765 (product code EBC)
- Cavity Liners under 21 CFR 872.3250 (product code EJK)

- Cavity Varnish under 21 CFR 872.3260 (product codes LBH, PHR, and PME)
- Denture Adhesives under the following regulations:
    - 21 CFR 872.3400 (product codes KOR, MMU, KOM)
    - 21 CFR 872.3410 (product codes KOL, KOQ, KXW)
    - 21 CFR 872.3420 (product code KOS)
    - 21 CFR 872.3450 (product codes KOP and KXX)
    - 21 CFR 872.3480 (product code KON)
    - 21 CFR 872.3490 (product codes KOO and KOT)
    - 21 CFR 872.3500 (product code KXY)

This guidance applies to dental composite resins that are combination products; however it does not address specific considerations unique to combination products.

Intended Use/Indications for Use:
The prosthetic devices that fall within the scope of this guidance are dental cements intended to serve as a temporary tooth filling or as a base cement to affix a temporary tooth filling, to affix dental devices such as crowns, bridges, or orthodontic brackets, or to be applied to a tooth to protect the tooth pulp and improve retention of a restoration. These devices are for prescription use only.

Device Design Characteristics:
The performance criteria in this guidance are applicable to dental cements as defined in the FDA-recognized consensus standards ISO 9917-1 *Dentistry – Water-based cements – Part 1: Powder/liquid acid-base cements* and ISO 9917-2 *Dentistry – Water-based cements Part 2: Resin-modified cements.*

ISO 9917-1 *Dentistry – Water-based cements – Part 1: Powder/liquid acid-base cements* is applicable to both hand-mixed and capsulated cements for mechanical mixing, where dental cements are categorized on the basis of their chemical composition as follows:

- Zinc phosphate cement
- Zinc polycarboxylate cement
- Glass polyalkenoate cement

ISO 9917-2 *Dentistry – Water-based cements Part 2: Resin-modified cements* classifies the materials used on the basis of their setting characteristics as follows:

- Class 1 Material: materials in which the setting reaction of the polymerizable component is activated chemically following mixing of components.
- Class 2 Material: materials in which the setting reaction of the polymerizable component is light activated.
- Class 3 Material: materials in which the setting reaction of the polymerizable component is activated chemically following mixing of components and may also be light-activated.

FDA may determine, on a case-by-case basis, that additional data are necessary to evaluate whether the device is appropriate for the Safety and Performance Based Pathway. In situations where you determine that additional testing outside of those identified in this guidance are necessary to determine whether the device is appropriate for the Safety and Performance Based

Pathway, we would encourage you to submit a Pre-Submission to engage in discussion with FDA prior to submission of the 510(k) as described in FDA guidance Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.

IV. Testing Performance Criteria

If your device is appropriate for submission through the Safety and Performance Based Pathway, and you choose to use that option, we do not expect you to provide direct comparison testing against a legally marketed predicate device to demonstrate substantially equivalent performance characteristics. To ensure that the performance criteria outlined in this guidance remain contemporary and take into account relevant data from recent clearances, FDA recommends that you provide a results summary for all tests evaluated in addition to the other submission information (e.g. Declaration of Conformity (DOC) [1]) recommended for each test or evaluation below. Consistent with FDA policy for all 510(k) submissions, for all 510(k) submissions under the Safety and Performance Based Pathway, FDA may request and review underlying data demonstrating that a new device meets the FDA-identified performance criteria and testing methodology, as necessary. Unless otherwise identified in the sections below, test information such as results summary, test protocols, and complete test reports should be submitted as part of the 510(k) as described in FDA's guidance Safety and Performance Based Pathway. For additional information regarding the submission of non-clinical bench testing information, please see FDA's guidance Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions.

1. **Test name:** Adhesive bond Strength
   Methodology: FDA-recognized versions of:
   - ISO 29022 *Dentistry -Adhesion – Notched-edge shear bond strength test* **or**

   Testing should be evaluated on dentin, enamel, and all other relevant surfaces (e.g. ceramic polymer, metal) that the subject device is intended for.
   Performance Criteria: Shear bond strength testing range between 5 MPa and 20 MPa, depending on application (e.g. temporary vs permanent, target surface material). If outside the range, provide a rationale based on intended application.
   Performance Criteria Source: Criteria are based on aggregated data submitted to FDA in 510(k) submissions for dental cements previously found to be substantially equivalent.
   Submission Information: DOC and summary table of results

2. **Test name:** Ion release profile (as applicable)
   Methodology: If the device includes a eluting agent, such as fluoride, calcium, or phosphorous ions, ion release profile testing should be conducted, including 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

[1] When you provide a DOC you are certifying that you are in conformance with that standard as defined in the guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices

concentration that sums each day's concentration with all previous measurements. During this test, the water should be replaced each day.
Performance Criteria: The elution profile should be equivalent to legally marketed devices of similar intended use.
Performance Criteria Source: Criteria are based on aggregated data submitted to FDA in 510(k) submissions for dental cements previously found to be substantially equivalent.
Submission Information: Release profile plot and testing protocol

3. **Test name:** Film Thickness (as applicable, luting cements only)
Methodology: FDA-recognized version of:
   - ISO 9917-1 *Water-based cements – Part 1: powder/liquid acid-base cements* **or**
   - ISO 9917-2 *Water-based cements – Part 2: Resin-modified cements*

Performance Criteria: Maximum film thickness of 25 µm
Performance Criteria Source: FDA-recognized version of:
   - ISO 9917-1 **or**
   - ISO 9917-2

Submission Information: DoC

4. **Test name:** Net Setting Time ($t_{setting}$)
Methodology: FDA-recognized version of:
   - ISO 9917-1 *Water-based cements – Part 1: powder/liquid acid-base cements* **or**
   - ISO 9917-2 *Water-based cements – Part 2: Resin-modified cements*

Performance Criteria:

Table 2: Dental Cement Net Setting Time Performance Criteria

	Luting Applications	Base/Lining Applications
Zinc Phosphate	2.5 min ≤ $t_{setting}$ ≤ 8 min	2 min ≤ $t_{setting}$ ≤ 6 min
Zinc Polycarboxylate	2.5 min ≤ $t_{setting}$ ≤ 8 min	2 min ≤ $t_{setting}$ ≤ 6 min
Glass Polyalkenoate	1.5 min ≤ $t_{setting}$ ≤ 8 min	1.5 min ≤ $t_{setting}$ ≤ 6 min
Resin-modified (Class 1 and Class 3 materials only)	$t_{setting}$ ≤ 8 min	$t_{setting}$ ≤ 6 min

Performance Criteria Source: FDA-recognized version of:
   - ISO 9917-1 **or**
   - ISO 9917-2

Submission Information: DOC

5. **Test name:** Compressive Strength (as applicable, powder/liquid acid-base cements only)
Methodology: FDA-recognized version of ISO 9917-1 *Water-based cements – Part 1: powder/liquid acid-base cements*
Performance Criteria:
   - Zinc phosphate: ≥50 MPa
   - Zinc polycarboxylate: ≥50 MPa

- Glass polyalkenoate: ≥50 MPa for luting and base/lining applications

Performance Criteria Source: FDA-recognized version of ISO 9917-1
Submission Information: DOC

6. **Test name:** Acid Erosion (as applicable, powder/liquid acid-base cements only)
Methodology: FDA-recognized version of ISO 9917-1 *Water-based cements – Part 1: powder/liquid acid-base cements*
Performance Criteria:
   - Zinc phosphate: ≤0.30mm
   - Zinc polycarboxylate: ≤0.40mm
   - Glass polyalkenoate: ≤0.17mm

Performance Criteria Source: ISO 9917-1
Submission Information: DOC

7. **Test name:** Working Time (as applicable, resin-modified cements only)
Methodology: FDA-recognized version of ISO 9917-2 *Water-based cements – Part 2: Resin-modified cements*
Performance Criteria: ≥1.5 minutes
Performance Criteria Source: FDA-recognized version of ISO 9917-2
Submission Information: DOC

8. **Test name:** Flexural Strength (as applicable, resin-modified cements only)
Methodology: FDA-recognized version of ISO 9917-2 *Water-based cements – Part 2: Resin-modified cements*
Performance Criteria: ≥10 MPA for luting and base/lining applications
Performance Criteria Source: FDA-recognized version of ISO 9917-2
Submission Information: DOC

9. **Test name:** Water sorption
Methodology: FDA-recognized version of ISO 4049 *Dentistry – Polymer-based restorative materials*
Performance Criteria: ≤ 40 $\mu g/mm^3$
Performance Criteria Source: FDA-recognized version of ISO 4049
Submission Information: DOC

10. **Test name:** Water solubility
Methodology: FDA-recognized version of ISO 4049 *Dentistry – Polymer-based restorative materials*
Performance Criteria: ≤ 7.5 $\mu g/mm^3$
Performance Criteria Source: FDA-recognized version of ISO 4049
Submission Information: DOC

Biocompatibility Evaluation

To identify the biocompatibility endpoints to include as part of your biocompatibility evaluation you should use Attachment A of the FDA guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk

management process, referred to in the rest of this document as the FDA Biocompatibility Guidance for brevity. FDA considers the devices covered by this guidance to be categorized as External Communicating Devices in contact with tissue/bone/dentin with a prolonged or permanent contact duration, and you should assess the endpoints below per Attachment A of the FDA Biocompatibility Guidance.

- Cytotoxicity
- Sensitization
- Oral Mucosa Irritation
- Acute Systemic Toxicity – Oral Application
- Subacute/Subchronic Toxicity – Oral Application
- Genotoxicity

Rationale in Lieu of Testing: If the subject device is manufactured from the identical raw materials using identical manufacturing processes as a predicate device with the same type and duration of tissue contact, and any changes in geometry are not expected to impact the biological response, this is typically sufficient to establish substantially equivalent biocompatibility, if documentation such as that outlined in Attachment F of the FDA Biocompatibility Guidance is also provided.

Testing: If you determined that testing is needed to address some or all of the identified endpoints, FDA recommends that complete test reports be provided for all tests performed unless a declaration of conformity without supplemental information can be appropriately provided, per Attachment E of the FDA Biocompatibility Guidance. Any test-specific positive, negative, and/or reagent controls should perform as expected, and protocol deviations should be thoroughly described and justified; however, note that certain protocol deviations may invalidate comparison to the performance criteria listed below. As described in the FDA guidance Safety and Performance Based Pathway, if a device cannot rely entirely on performance criteria identified by FDA to demonstrate substantial equivalence for its submission, it is not appropriate for the Safety and Performance Based Pathway program; however, the previously established 510(k) programs in which direct performance comparisons against appropriate predicates are conducted, including Traditional, Special, or Abbreviated 510(k), remain available.

11. **Test name:** Biocompatibility endpoints (identified from FDA Biocompatibility Guidance)
Methodology: FDA-recognized versions of biocompatibility consensus standards
    - ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
    - ISO 7405 *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry* (this standard is an application of ISO 10993-1 to dental devices)

    Performance Criteria: All direct tissue contacting components of the device and device-specific instruments should be determined to have an acceptable biological response.
Performance Criteria Source: The FDA Biocompatibility Guidance
Additional Considerations: For any biocompatibility test samples with an adverse biological response, the biocompatibility evaluation should explain why the level of toxicity seen is acceptable. Some comparison testing against a legally marketed predicate

may be necessary (and is considered acceptable under the Safety and Performance Based Pathway) to support such a rationale as explained in the FDA Biocompatibility Guidance. For standard biocompatibility test methods that include comparison device control samples, the legally marketed comparison device control samples should perform as expected.

Submission Information: Refer to FDA Biocompatibility Guidance

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