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Dental Ceramics – 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 OHT1/DHT1B: Division of Dental and ENT 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 20852-1740. Identify all comments with the docket number [FDA-2024-D-4169]. 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 to receive a copy of the guidance. Please include the document number GUI00007014 and complete title of the guidance in the request.

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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 ceramics in support of the Safety and Performance Based Pathway. Under this framework, submitters (you) planning to submit a 510(k) using the Safety and Performance Based Pathway for dental ceramics 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 dental ceramics to determine the performance criteria and associated testing methods that could support a finding of substantial equivalence for dental ceramics 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 includes dental ceramics. These Class II devices and are regulated under 21 CFR 872.6660, Porcelain powder for clinical use (product code EIH), and under 21 CFR 872.3920, Porcelain tooth (product code ELL).

The following devices are outside the scope of this guidance:

- Posterior artificial teeth with metal inserts under 21 CFR 872.3900 (product code ELJ)[1]
- Backing and facing for artificial teeth under 21 CFR 872.3910 (product code ELK)[1]
- Endosseous dental implants under 21 CFR 872.3640 (product codes DZE, NRQ, and OAT)
- Endosseous dental implant abutments under 21 CFR 872.3630 (product code NHA)
- Temporary crown and bridge resin under 21 CFR 872.3770 (product codes EBG and POW)
- Tooth shade resin material under 21 CFR 872.3690 (product code EBF)
- Bone grafting materials under 21 CFR 872.3930

[1] This Class I device is considered exempt from premarket notification. However, if the limits of exemption in 21 CFR 872.9 are exceeded and premarket notification would be required, then the device would be outside the scope of this guidance.

Intended Use/Indications for Use:
The dental ceramics that fall within the scope of this guidance document are devices consisting of a mixture of kaolin, felspar, quartz, or other substances intended for use in the production of artificial teeth in fixed or removable dentures, of jacket crowns, facings, bridges, and veneers. The devices are used in prosthetic dentistry by heating the powder mixture to a high temperature in an oven to produce a hard restoration or prosthesis with a glass-like finish. These devices are for prescription use only.

Device Design Characteristics:
The following types of dental ceramic materials are within the scope of this guidance and are defined in the FDA-recognized consensus standard ISO 6872 *Dentistry – Ceramic materials:*

— Type I: Ceramic products that are provided as powders, pastes, or aerosols.

— Type II: All other forms of ceramic products.

Within ISO 6872, dental ceramics are further divided into five classes according to their intended clinical use and indications as follows:

— Class 1:

a) Monolithic ceramic for single-unit anterior prostheses, veneers, inlays, or onlays adhesively cemented.

b) Ceramic for coverage of a metal framework or a ceramic substructure.

— Class 2:

a) Monolithic ceramic for single-unit anterior or posterior prostheses adhesively cemented.

b) Partially or fully covered substructure ceramic for single-unit anterior or posterior prostheses adhesively cemented.

— Class 3:

a) Monolithic ceramic for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration, adhesively or non-adhesively cemented.

b) Partially or fully covered substructure for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration, adhesively or non-adhesively cemented.

— Class 4:

a) Monolithic ceramic for three-unit prostheses involving molar restoration.

b) Partially or fully covered substructure for three-unit prostheses involving molar restoration.

— Class 5:

Monolithic ceramic for prostheses involving partially or fully covered substructure for four or more units or fully covered substructure for prostheses involving four or more units.

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) [2]) 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:** Flexural strength
   Methodology: FDA-recognized version of ISO 6872 *Dentistry – Ceramic materials*
   Performance Criteria: The performance criteria are defined based on the recommended clinical indications as follows:

[2] 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.

Material Classification	Flexural strength [MPa] Minimum value for mean
Class 1	50
Class 2	100
Class 3	300
Class 4	500
Class 5	800

Performance Criteria Source: FDA-recognized version of ISO 6872
Submission Information: DOC

2. **Test name:** Chemical solubility
Methodology: FDA-recognized version of ISO 6872 *Dentistry – Ceramic materials*
Performance Criteria: The performance criteria are defined based on the recommended clinical indications as follows:

Material Classification	Chemical solubility [µg/cm^2]
Class 1a	<100
Class 1b	<100
Class 2a	<100
Class 2b	<2000
Class 3a	<100
Class 3b	<2000
Class 4a	<100
Class 4b	<2000
Class 5	<100

Performance Criteria Source: FDA-recognized version of ISO 6872
Submission Information: DOC

3. **Test name:** Fracture toughness
Methodology: FDA-recognized version of ISO 6872 *Dentistry – Ceramic materials*
Performance Criteria: The performance criteria are defined based on the recommended clinical indications as follows:

Material Classification	Fracture toughness [MPa√m] Minimum
Class 1	0.7
Class 2	1.0
Class 3	2.0
Class 4	3.5
Class 5	5.0

Performance Criteria Source: FDA-recognized version of ISO 6872

Additional Considerations: Fracture toughness testing is typically conducted on fully covered substructure ceramic. Partially covered substructure ceramic may be omitted from this testing.
Submission Information: DOC

4. **Test name:** Radioactivity
Methodology: FDA-recognized version of ISO 6872 *Dentistry – Ceramic materials*
Performance Criteria: Activity concentration ≤ 1.0 $Bq \cdot g^{-1}$ of ^{238}U.
Performance Criteria Source: FDA-recognized version of ISO 6872
Submission Information: DOC

5. **Test name:** Linear thermal expansion coefficient
Methodology: FDA-recognized version of ISO 6872 *Dentistry – Ceramic materials*
Performance Criteria: The coefficient of thermal expansion of the ceramics should not deviate by more than 0.5×10^{-6} K^{-1} from the value stated by the manufacturer.
Performance Criteria Source: FDA-recognized version of ISO 6872
Submission Information: DOC

6. **Test name:** Glass transition temperature
Methodology: FDA-recognized version of ISO 6872 *Dentistry – Ceramic materials*
Performance Criteria: The glass transition temperature of the ceramics should not deviate by more than 20 °C from the value stated by the manufacturer.
Performance Criteria Source: FDA-recognized version of ISO 6872
Submission Information: DOC

Biocompatibility Evaluation

To identify the biocompatibility endpoints to include as part of your biocompatibility evaluation you should use Attachment A of 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, referred to in the rest of this document as the CDRH 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 of >30 days 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.

5. **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