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Dental Impression Materials – Performance Criteria for Safety and Performance Based Pathway

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Guidance for Industry and Food and Drug Administration Staff

GUIDANCE

Document issued on September 30, 2024.

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-4170]. 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 GUI00007013 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 impression materials 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 impression materials 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 impression materials to determine the performance criteria and associated testing methods that could support a finding of substantial equivalence for dental impression materials 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 devices that are the subject of this guidance are dental impression materials intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures. These devices are Class II and are regulated under 21 CFR 872.3660, with the product code ELW.

The following are outside the scope of this guidance:

- Optical impression systems for CAD/CAM under 21 CFR 872.3661 (product code KZN, NOF, QJK)
- Resin impression tray material under 21 CFR 872.3670 (product code EBH)
- Preformed impression tray under 21 CFR 872.6880 (product code EHY)
- Impression tube under 21 CFR 872.6570 (product code KCQ)

Intended Use/Indications for Use:

The devices that fall within the scope of this guidance document are dental impression materials such as alginate or polysulfide intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums. Dental impression materials are intended to

provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures. These devices are for prescription use only.

Device Design Characteristics:
The following types of dental impression materials are within the scope of this guidance and are defined in the FDA-recognized version of ISO 4823 *Dentistry - Elastomeric impression and bite registration materials*:

— Type 0: putty consistency;

— Type 1: heavy-bodied consistency;

— Type 2: medium-bodied consistency;

— Type 3: light-bodied consistency; and

— Type B: bite registration materials.

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 make a determination regarding eligibility into 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 below for each test or evaluation. 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] 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.

For Material Types 0-3

1. **Test name:** Consistency (test disc diameter)
Methodology: FDA-recognized version of ISO 4823 *Dentistry - Elastomeric impression and bite registration materials*
Performance Criteria:

Material Type	Test Disc Diameter (mm)
Type 0 & 1	35 mm maximum
Type 2	31 mm minimum; 41 mm maximum
Type 3	36 mm minimum

Performance Criteria Source: FDA-recognized version of ISO 4823
Submission Information: DOC

2. **Test name:** Detail reproduction (line width reproduced)
Methodology: FDA-recognized version of ISO 4823 *Dentistry - Elastomeric impression and bite registration materials*
Performance Criteria:

Material Type	Line Width Reproduced (µm)
Type 0	75 µm
Type 1	50 µm
Type 2 & 3	20 µm

Performance Criteria Source: FDA-recognized version of ISO 4823
Submission Information: DOC

3. **Test name:** Linear dimensional change
Methodology: FDA-recognized version of ISO 4823 *Dentistry - Elastomeric impression and bite registration materials*
Performance Criteria: ≤1.5%
Performance Criteria Source: FDA-recognized version of ISO
Submission Information: DOC

4. **Test name:** Compatibility with gypsum (line width reproduced)
Methodology: FDA-recognized version of ISO 4823 *Dentistry - Elastomeric impression and bite registration materials*
Performance Criteria:

Material Type	Line Width Reproduced (µm)
Type 0	75 µm
Type 1, 2, & 3	50 µm

Performance Criteria Source: FDA-recognized version of ISO 4823
Submission Information: DOC

5. **Test name:** Elastic recovery
   Methodology: FDA-recognized version of ISO 4823 *Dentistry - Elastomeric impression and bite registration materials*
   Performance Criteria: ≥96.5%
   Performance Criteria Source: FDA-recognized version of ISO 4823
   Submission Information: DOC

6. **Test name:** Strain in compression
   Methodology: FDA-recognized version of ISO 4823 *Dentistry - Elastomeric impression and bite registration materials*
   Performance Criteria:

Material Type	Strain in Compression (%)
Type 0 & 1	0.8% minimum; 20% maximum
Type 2 & 3	2% minimum; 20% maximum

   Performance Criteria Source: FDA-recognized version of ISO 4823
   Submission Information: DOC

For Material Type B

7. **Test name:** Linear dimensional change
   Methodology: FDA-recognized version of ISO 4823 *Dentistry - Elastomeric impression and bite registration materials*
   Performance Criteria: ≤1.5%
   Performance Criteria Source: FDA-recognized version of ISO 4823
   Submission Information: DOC

8. **Test name:** Compression set
   Methodology: FDA-recognized version of ISO 4823 *Dentistry - Elastomeric impression and bite registration materials*
   Performance Criteria: ≤0.1 mm
   Performance Criteria Source: FDA-recognized version of ISO 4823
   Submission Information: DOC

9. **Test name:** Hardness (Shore A)
   Methodology: FDA-recognized version ISO 4823 *Dentistry - Elastomeric impression and bite registration materials*
   Performance Criteria: ≥50 (Shore A)
   Performance Criteria Source: FDA-recognized version of ISO 4823
   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 surface devices in contact with mucosal membrane with a limited contact duration of ≤24 hours and you should assess the endpoints below per Attachment A of the CDRH Biocompatibility Guidance.

- Cytotoxicity
- Sensitization
- Oral Mucosa Irritation

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 or in manufacturing processes 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, and Abbreviated 510(k)s, remain available.

10. **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