Denture Base Resins – Performance Criteria for Safety and Performance Based Pathway

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE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

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Denture Base Resins – Performance Criteria for Safety and Performance Based Pathway

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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This draft guidance provides performance criteria for denture base resins in support of the Safety and Performance Based Pathway.[1] Under this framework, submitters (you) planning to submit a 510(k) using the Safety and Performance Based Pathway for denture base resins will have the option to use the performance criteria proposed in this draft guidance to support substantial equivalence, rather than a direct comparison of the performance of the subject device to that of a predicate device.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.[2] 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.[3]

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless

[1] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway

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

[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Scope/Device Description

Devices that are the subject this guidance are denture base resins. These devices are Class II and are regulated under 21 CFR 872.3760, Denture relining, repairing, or rebasing resin, with the product code EBI.

Intended Use/Indications for Use:
The prosthetic devices that fall within the scope of this guidance are for denture rebasing resin composed of materials such as methyl methacrylate, intended to reline a denture surface that contacts tissue, to repair a fractured denture, or to form a new denture base. These devices are not available for over-the-counter (OTC) use.

These devices are intended for the fabrication of patient-specific denture bases for full or partial dentures. The scope of this guidance does not include resins for OTC relining or repairing denture bases, preformed denture teeth, or partially fabricated denture kits which are classified elsewhere (see 21 CFR 872.3560, 872.3570, 872.3580, 872.3590 and 872.3600, respectively).

The following types and classes of polymers/materials (Types 1-5) are within the scope of this guidance and are defined in the FDA-recognized consensus standard ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers*:

- Type 1: Heat-polymerizable materials
  - Class 1: Powder and liquid
  - Class 2: Plastic cake
- Type 2: Autopolymerizable materials
  - Class 1: Powder and liquid
  - Class 2: Powder and liquid for pour-type resins
- Type 3: Thermoplastic blank or powder
- Type 4: Light-activated materials
- Type 5: Microwave cured materials

Device Design Characteristics:
The performance criteria in this guidance are applicable to the classes of resins (Types 1-5).

Additively Manufactured Denture Resins:
For additively manufactured (3D printed) denture resins, we recommend that you reference FDA's guidance Technical Considerations for Additive Manufactured Medical Devices.[4] additional information, not specifically addressed in ISO 20795-1, should be included in a premarket submission. This includes:

[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-additive-manufactured-medical-devices

- identification of each workflow and system(s) (e.g., the specific scanner, software, printer, cure unit, etc., employed) that is validated together for interoperability for fabricating the device;
- printing parameters (e.g., addition of support material, slicing, build path, instantaneous power of energy delivery system, environmental conditions, etc.);
- as additive manufacturing allows different print directions within the build space relative to the device/part orientation and/or to print more than one device/part simultaneously at different build plate locations, identification of the build volume placement (e.g., acceptable part orientation, build plate location, and other parametric considerations) and build repeatability manufacturing process information validated under your acceptance activities to ensure reproducibility and consistency within a build cycle and across print run lots;
- if applicable, leftover material reuse process for the validated additive manufacturing method. This may include, but is not be limited to, a limit for number of print runs for using leftover reused material, limit to percent of leftover reused material (for example 1:1 mixture of virgin and leftover reused materials), recycling processes such as filtering leftover material, or monitoring for changes in chemistry, water content, etc.;
- instructions for the end user (if fabricated at point-of-care), including information on setup and on-site validation, reuse of leftover resin material between print runs, and cleaning after final device printing;
- a verification and validation report of dimensional measurements demonstrating that the physical output of the system for fabricating the device meets design input specifications for critical dimensions within pre-specified tolerances for the device type and intended use to demonstrate consistency and reproducibility between build cycles made on samples from multiple build cycles; and
- performance testing considerations for additively manufactured devices (see Section III below).

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[5] to engage in discussion with FDA prior to submission of the 510(k).

III. Testing Performance Criteria

If your device is appropriate for submission through the Safety and Performance Based Pathway, and you choose to use that option, you do not need 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

[5] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

you provide a results summary for all tests evaluated in addition to the other submission information (e.g., Declaration of Conformity (DoC)) identified for each test or evaluation below. Unless otherwise identified in the performance criteria sections below, test information such as results summary, test protocols, or complete test reports should be submitted as part of the 510(k) as described in FDA's guidance Safety and Performance Based Pathway.[6] For additional information regarding the submission of non-clinical bench testing information, refer to FDA's guidance Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions.[7]

Mechanical Bench Testing

1. **Test name:** Ultimate flexural strength
   Methodology: ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers*
   Performance Criteria:
   Types 1, 3, 4, and 5 polymers: ≥ 65 MPa
   Type 2 polymers: ≥ 60 MPa
   Performance Criteria Source: ISO 20795-1 (2013) *Dentistry – Base polymers – Part 1: Denture base polymers*
   Submission Information: DoC

2. **Test name:** Flexural modulus
   Methodology: ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers*
   Performance Criteria:
   Types 1, 3, 4, and 5 polymers: ≥ 2000 MPa
   Type 2 polymers: ≥ 1500 MPa
   Performance Criteria Source: ISO 20795-1 (2013) *Dentistry – Base polymers – Part 1: Denture base polymers*
   Submission Information: DoC

3. **Test name:** Stress intensity factor
   Methodology: ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers*
   Performance Criteria: Types 1-5 polymers: ≥ 1.9 MPa • $m^{1/2}$
   Performance Criteria Source: ISO 20795-1 (2013) *Dentistry – Base polymers – Part 1: Denture base polymers*
   Submission Information: DoC

4. **Test name:** Fracture work
   Methodology: ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers*
   Performance Criteria: Types 1-5 polymers: ≥ 900 J/m^2
   Performance Criteria Source: ISO 20795-1 (2013) *Dentistry – Base polymers – Part 1: Denture base polymers*

[6] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway

[7] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket

Submission Information: DoC

5. **Test name:** Residual monomer
Methodology: ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers*
Performance Criteria:
Types 1, 3, 4, and 5 polymers: ≤ 2.2% mass fraction of methyl methacrylate
Type 2 polymers: ≤ 4.5% mass faction of methyl methacrylate
Performance Criteria Source: ISO 20795-1 (2013) *Dentistry – Base polymers – Part 1: Denture base polymers*
Submission Information: DoC

6. **Test name:** Water sorption
Methodology: ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers*
Performance Criteria: Types 1-5 polymers: ≤ 32 $\mu g/mm^3$
Performance Criteria Source: ISO 20795-1 (2013) *Dentistry – Base polymers – Part 1: Denture base polymers*
Submission Information: DoC

7. **Test name:** Water solubility
Methodology: ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers*
Performance Criteria:
Types 1, 3, 4, and 5 polymers: ≤ 1.6 $\mu g/mm^3$
Type 2 polymers: ≤ 8 $\mu g/mm^3$
Performance Criteria Source: ISO 20795-1 (2013) *Dentistry – Base polymers – Part 1: Denture base polymers*
Submission Information: DoC

Additive Manufacturing Testing Considerations

The performance criteria above also apply to additively manufactured denture base resins.

The following tests are based on a loading force directionally applied to the devices and the evaluation of resulting failure modes:

- ultimate flexural strength;
- flexural modulus;
- stress intensity factor; and
- fracture work.

Therefore, performance testing for additively manufactured devices should additionally account for the layer-by-layer process of additive manufacturing where the imparted directionality from the printing process (i.e., anisotropy) may affect the final device properties. You should assess the variability of mechanical performance under loading across the multiple device configurations available based on the build volume placement (e.g., part orientation, build plate location, and other parametric considerations) and leftover material reuse parameters, as described in Section II. For these four bulleted mechanical bench tests above, we recommend

you provide testing that evaluates clinically relevant worst-case scenarios for build orientation based on available print directions (e.g., x, y, or z-axis), build plate locations (e.g., center vs. corner), and leftover material reuse procedures (if applicable) to show the final printed device properties remain within pre-specified ranges. The number of test runs or build cycles will be dependent on your printing strategy and worst-case analysis.

For the following three tests, the layer-by-layer process of additive manufacturing is not expected to affect test result variability and a loading force is not directionally applied:

- residual monomer;
- water sorption; and
- water solubility.

Therefore, only one test run or build cycle for each test is needed using any available device configuration within the confines of the validated manufacturing process considerations of build volume placement (e.g., part orientation, build plate location, and other parametric considerations) and leftover material reuse parameters, as described in Section II.

Biocompatibility Evaluation

To identify the biocompatibility endpoints to include as part of your biocompatibility evaluation you should use Attachment A of the Center for Devices and Radiological Health's (CDRH) guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,[8] 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 permanent contact duration of >30 days and you should assess the endpoints below per Attachment A of the CDRH Biocompatibility Guidance.

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity

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 CDRH 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

[8] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and

a declaration of conformity without supplemental information can be appropriately provided, per Attachment E of the CDRH 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 and require submission of a Traditional, Special, or Abbreviated 510(k).

8. **Test name:** Biocompatibility endpoints (identified from CDRH Biocompatibility Guidance)
   Methodology: FDA currently-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 contacting components of the device and device-specific instruments should be determined to have an acceptable biological response.
   Performance Criteria Source: The CDRH 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 CDRH Biocompatibility Guidance. For standard biocompatibility test methods that include comparison device control samples, the legally marketed comparison device control samples should perform as expected, as specified above for the subject device samples.
   Submission Information: Refer to CDRH Biocompatibility Guidance