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Endosseous Dental Implants and Endosseous Dental Implant Abutments – 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

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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-4409]. Comments may not be acted upon by the Agency until the document is next revised or updated.

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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 endosseous dental implants and endosseous dental implant abutments 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 endosseous dental implants and abutments 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 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 endosseous dental implants and abutments to determine the performance criteria and associated testing methods that could support a finding of substantial equivalence for endosseous dental implants and abutments 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 include root-form endosseous dental implants and endosseous dental implant abutments. These devices are Class II devices and are regulated under 21 CFR 872.3640, endosseous dental implant (product code DZE) and 21 CFR 872.3630, endosseous dental implant abutment (product code NHA).

Intended Use/Indications for Use:
The endosseous dental implant devices ('implant bodies') that fall within the scope of this guidance are root-form and are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The endosseous dental implant abutment device ('abutment') is intended to be used with the root-form endosseous dental implant to aid in prosthetic rehabilitation.

Device Design Characteristics:

The dental implant bodies and abutments that fall within the scope of this guidance document should be manufactured solely from one of the following materials in conformance with the associated FDA-recognized version of the following consensus standards:

- ASTM F67 *Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)*
- ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*
- ASTM F1295 *Standard Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700)*

The following characteristics should be described for each component included in the submission and compared between the subject and predicate devices. We recommend the use of engineering drawings to describe these features. If the devices include a range features such as lengths and diameters, it is best to present summary engineering drawings with ranges.

- Abutment characteristics:
    - Diameter
    - Wall thickness
    - Transmucosal height
    - Post height (portion above the transmucosal collar)
    - Angle[1]
    - Retention type to implant body, including dimensions of screw if applicable
    - Dental restoration retention type

- Implant body characteristics:
    - Connection platform type and dimensions, if applicable
    - Bone diameter
    - Placement type, *i.e.*, bone level, tissue level, sub-crestal
    - Transmucosal height, if applicable
    - Threaded length
    - Retention length
    - Thread type

FDA considers the final finished device to include both the in-bone structure and the section that mimics the prepared tooth or allows for the restoration of chewing function. For a device under product code DZE that does not include an abutment post, you should include in your 510(k) a compatible device that would fall under the NHA product code, or identify a legally marketed

[1] FDA considers angulation to be the angle of the implant axis with the occlusal load. Discussion of "angulation" includes both the nominal angulation of the abutment and any additional angulation based on the placement of the final construct. For instance, certain overdenture type abutments often are able to correct angled placement of the implant body by incorporating the angular correction into the overdenture retention features, even if the abutments are not placed at an angle in reference to the implant axis. FDA considers this type of abutment to be an "angled" abutment due to its non-parallel alignment with the occlusal load.

device under the NHA product code. Likewise, an NHA device should identify a legally marketed compatible DZE device.

If you are not able to establish implant to abutment compatibility based solely on descriptive information because, for example, you cannot obtain the manufacturing tolerances for the platform size and shape of another manufacturer's device, we recommend that you provide the steps taken to establish implant to abutment compatibility, such as a reverse engineering analysis report.

If needed to show compatibility, the reverse engineering analysis should be performed on the original equipment manufacturer (OEM) implant body, OEM abutment(s), and OEM abutment screw, if applicable. The devices used should not be analogs or replicas. The submission should describe each device that is intended to be compatible, including the 510(k) clearance number(s), manufacturer name, implant system name, and dimensions. The reverse engineering analysis should include the following:

1. Description and tolerances of the measuring device(s) used, such as an optical measuring machine, tomography, calipers, *etc*.
2. The sample size, including justification, for each OEM component used in the reverse engineering analysis.
3. A chart for each component, including the following information:
    a. Identification of the critical features analyzed for the OEM component and the proposed device, including images as applicable.
    b. Average measured value
    c. Standard deviation of the measure value
    d. Upper tolerance limit
    e. Lower tolerance limit
4. A summary of the plan that is part of your quality system, which includes the method and frequency to which the device's compatibility with each OEM device will be tested and confirmed, in the case of an OEM change in design.
5. Representative computer aided design (CAD) images for the subject implant system and OEM implant system for each connection type per manufacturer. The CAD images should include cross sections in both the coronal and transverse planes. The images should be in contrasting colors to show gaps and/or tolerances between components of the system.

Dental implant bodies and abutments with the following features are outside the scope of this guidance:

- Two-piece abutments that are composed of a base part combined with a computer aided design and/or computer aided manufacturing (CAD/CAM) top half
- Abutments with a post height of less than 4 mm
- Implants that have a diameter of less than 3.25 mm or a length less than 7.0 mm
- Abutments that are retained to the implant body by methods other than screw retention
- Dental implant bodies that are placed outside of the alveolar ridge, including zygomatic implants and abutments intended for use with zygomatic implants
- Additively manufactured devices

- Implant bodies that are provided non-sterile
- Coated implant bodies
- Devices with statements on superior clinical performance (e.g., faster osseointegration, less bone loss), specifically those necessitating testing beyond the scope of this guidance (e.g., animal or clinical testing) to support the statement
- New technology, i.e., technology different from that used in a legally marketed implant or abutment
- Designs dissimilar from designs previously cleared
- An angulation of the accompanying or recommended implant abutment greater than 30°

Some of the recommendations in this safety and performance guidance may assist in complying with some of the special controls for endosseous dental implants and abutments. For information regarding the special controls for endosseous dental implants and abutments, see Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments. Additional information that is beyond the scope of this safety and performance guidance document regarding submission of a 510(k) for endosseous dental implants and abutments, such as device description and labeling, can be found in the above guidance.

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 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 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. For additional information regarding the submission of non-clinical bench

[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.

testing information, please see FDA's guidance Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions.

Mechancical Bench Testing

1. **Test name:** Dynamic Loading Test (as applicable for systems that include angled abutments)
   Methodology: FDA-recognized version of ISO 14801 *Dentistry - Implants - Dynamic loading test for endosseous dental implants* and Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments
   Performance Criteria: The worst case construct should reach the maximum endured load based on the major thread diameter of the implant body as follows:

Major Thread Diameter (mm)	Maximum endured load (N)
3.0, 3.1, 3.2, 3.3	150
3.4, 3.5	170
3.6	180
Greater than 3.6	200

   For implant bodies with nominal diameters that do not match a value in the table above, a comparison should be made to the next highest major diameter listed (e.g., a 3.35 mm implant body should use the 3.4 mm acceptance criteria).
   Performance Criteria Source: Criteria and associated warnings are derived from aggregated mechanical testing data and labeling submitted to FDA in 510(k) submissions for dental implant and abutment devices previously found to be substantially equivalent.
   Additional Considerations: Representative devices that are intended and/or labeled to be placed at an angle in excess of the nominal angulation of the abutment should be tested at the largest intended angulation plus 10° of uncorrected angulation. You should include relevant information outlined by ISO 14801, including the determination and engineering drawing of the worst case, calculation or measurement of the moment arm, the physical set up of the testing method, method for eliminating lateral constraints, and mode of failure near the maximum endured load in your test report. We recommend that you define the steps between loading values to be small enough so that the maximum endured load is clearly defined.

   In addition to reaching the maximum endured load as defined above we recommend including warnings, such as those below, in your device labeling based on the maximum endured load of the subject system (consistent with section 13 of Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments).
   - Maximum endured load is at 150 N: "Warning: (device name) are indicated for maxillary lateral and mandibular central/lateral incisors only."

- Maximum endured load is below 300 N but above 150 N: "Warning: Small diameter implants and angled abutment are not recommended for the posterior region."
- Maximum endured load is below 400 N but above 300 N: "Warning: Small diameter implants and angled abutment not recommended for the molar region."

Submission Information: A full test report should be provided.

2. **Test name:** Surface Cleanliness Analysis for Blasted or Roughened Implants
Methodology: You should provide analysis of the surface of the implant body, using scanning electron microscope (SEM) and energy dispersive X-ray spectroscopy (EDS), or similar technology that allows for magnified images of the implant surface and determination of the surface elemental composition. The magnified images should be of sufficient magnification to show the entire representative surface of the implant. The sample size should be adequately justified and the testing should include test articles from multiple manufacturing lots. Test articles should undergo all manufacturing processes before being tested, including packaging and sterilization. The spectroscopy analysis should clearly define the locations being analyzed, especially in instances where the magnified images suggest foreign bodies or particulate matter.
Performance Criteria: SEM and EDS analysis should demonstrate that there are no particles on the surface and that all chemicals have been washed from the surface.
Performance Criteria Source: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments
Submission Information: The submission should include the magnified images, the spectroscopy analysis, and sample size justification. The sample justification should clearly demonstrate how the locations analyzed on the implant bodies are representative of the entire surface undergoing any treatment.

Sterilization (devices labeled as sterile) and Reprocessing (end-user sterilized) Validation

3. **Test name:** Sterilization (devices labeled as sterile) and Reprocessing (end-user sterilized)
Methodology: FDA currently-recognized version of the following consensus standards (as applicable):
    - ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*
    - ISO 11135 *Sterilization of health care products – Ethylene oxide Requirements for development, validation, and routine control of a sterilization process for medical devices*
    - ISO 11137-1 *Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*
    - ISO 20857 *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

- AAMI/ANSI/ISO 11607-1 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- AAMI/ANSI/ISO 11607-2 *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*
- ASTM F88 *Standard Test Method for Seal Strength of Flexible Barrier Materials*
- ASTM F3039 *Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration*
- ASTM F2096 *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)*

Performance Criteria: Validation testing should demonstrate the cleanliness and sterility of, or the ability to clean and sterilize to a sterility assurance level of 10^{-6}, the device and device-specific instruments. You should provide a description of the sterile barrier system and how it will maintain the device's sterility, and a description of the package test methods, but not package test data. If the sterile barrier system is single layered, you should include adequate instructions in your labeling related to the unpackaging process, and a usability evaluation for aseptic presentation, as described in section 7 of the FDA recognized standard, AAMI/ANSI/ISO 11607-1 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems,* that demonstrates that the end user can unpackage the device without contamination. For devices that are provided sterile, endotoxin-mediated pyrogenicity information, as described in section V.A.4 of FDA guidance Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, should be provided. For any device that is provided non-sterile or is intended to be modified by the end user, you should provide instructions with a validated sterilization cycle as described in Appendix C of FDA guidance Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.

Performance Criteria Source: FDA's guidance:

- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile

Submission Information: If using an Established Category A sterilization method, you should provide the information in Section V.A. of the FDA guidance Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile; the validation data itself is not needed to demonstrate substantial equivalence.

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 FDA Biocompatibility Guidance for brevity. FDA considers endosseous dental implants and endosseous dental implant abutments to be categorized as implanted devices in contact with tissue/bone with a prolonged or permanent contact duration of > 30 days. Thus, you should assess the endpoints below, per Attachment A of the FDA Biocompatibility Guidance.

- Cytotoxicity

- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Sub-acute/Sub-chronic Toxicity
- Genotoxicity
- Implantation
- Chronic Toxicity
- Carcinogenicity

Rationale in Lieu of Testing: If the subject device is manufactured from the identical raw materials using identical manufacturing processes as your own 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. Please be advised that this rationale is only approriate if you have complete knowledge of the manufacturing process used to create the predicate device.

In addition, if the subject device is manufactured from material that conforms to a standard for implantable medical devices (ASTM F136, ASTM F67, or ASTM F1295), and has been shown to have a clean surface via SEM/EDS or similar analysis, FDA recommends providing biocompatibility testing to demonstrate that no materials that may cause a negative biological reaction have been introduced via the proprietary manufacturing processes. Generally this includes cytotoxicity, sensitization, and irritation testing. Based on historical data, FDA believes this information is generally sufficient to demonstrate substantially equivalent biocompatibility of these devices.

Testing: f 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. Please be advised that you should use a surface area calculation for extraction volume, instead of weight, unless you demonstrate that using weight results in a higher ratio of test article per volume. 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.

5. **Test name:** Biocompatibility endpoints (identified from FDA Biocompatibility Guidance)
Methodology: Current FDA-recognized versions of biocompatibility consensus standards
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