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Air Powered Dental Handpieces and Air Motors – Performance Criteria for Safety and Performance Based Pathway

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Guidance for Industry and Food and Drug Administration Staff

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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. Identify all comments with the docket number [FDA-2024-D-4168]. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Air-Powered Dental Handpieces and Air Motors – Performance Criteria for Safety and Performance Based Pathway

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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 air powered or contra- and right-angle attachment dental handpieces and air motors 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 these devices 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 guidance 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 devices that are the subject of this guidance are dental air powered handpieces and air motors (product code EFB) or contra- and right-angle attachment (product code EGS). These are Class I (reserved) devices regulated under 21 CFR 872.4200. The scope of this guidance includes devices where the main body is constructed of metal, for example stainless steel or titanium, with a maximum rotational speed of 450,000 revolutions per minute (RPM) that are intended to be end-user sterilized.

The dental handpieces that are the subject of this guidance are intended for use in general dentistry including the following functions: cutting and grinding teeth; cavity preparations; tooth and crown preparation; and finishing and trimming teeth and filling materials.

Intended Use/Indications for Use:
The dental handpieces that fall within the scope of this guidance document are air-powered dental handpieces and air motors intended for general dentistry. These devices are prescription use devices.

Dental handpieces with the following intended uses or characteristics are not within the scope of this guidance:

- Main body of the device made from non-metallic materials
- Handpieces also regulated under 21 CFR 872.4200 with electrical, battery, internal light source or software components, or other power sources:
    - EBW; Controller, Foot, Handpiece and Cord
    - EFA; Handpiece, Belt and/or Gear Driven, Dental
    - EKX; Handpiece, Direct Drive, AC-Powered
    - EKY; Handpiece, Water-Powered
- Prophy Handpieces
- Handpieces with different intended uses or under other classification regulations:
    - Bone Cutting Instruments and Accessories under 21 CFR 872.4120
        - DZH; Saw, Bone, AC-Powered
        - DZI; Drill, Bone, Powered
        - DZJ; Driver, Wire, And Bone Drill, Manual
        - KMW; Handpiece, Rotary Bone Cutting
    - Ultrasonic Scalers under 21 CFR 872.4850
        - ELC; Scaler, Ultrasonic
- Single use handpieces
- Handpieces not intended to be user sterilized (e.g., provided sterile, high-level disinfected)

Device Design Characteristics:
The subject devices are prescription use air-powered dental handpieces and air driven motors that are used by trained dental professionals for removal of carious material, cavities, crown preparations, and as a surgical tool for impacted third molar removal and periodontal procedures. The air-powered dental handpiece and motors use compressed air as a power source to drive the turbine in the head of the handpiece to generate drill rotation for dental procedures. The handpiece is designed with a head with a chunking mechanism for insertion of dental files/shanks with a straight or angled body. The base of the handpiece contains holes for drive air, spray air, and/or spray water to go through by connection to an air motor or a hose connection.

The air motor may consist of the housing, handpiece connection, and coupling for hose connection (i.e., air and water supply). The air motor converts compressed air into mechanical rotation energy. Compressed air runs into the air motor and transfers energy by a coupling to a straight or angled handpiece, which is connected to the motor.

General guidance that is beyond the scope of this safety and performance guidance document regarding submission of a 510(k) for dental handpieces (i.e., labeling) can be found in FDA's guidance Dental Handpieces – Premarket Notification [510(k)] Submissions.

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 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, 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 testing information, please see FDA's guidance Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions. For information about supplemental documentation that should be included with a DOC, see FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.

Mechanical Bench Testing

We recommend providing one Test Report Form and one DOC to ISO 14457 for tests in this section.

1. **Test name:** I-Drop test
   Methodology: FDA-recognized version of (International Organization for Standardization) ISO 14457 *Dentistry – Handpieces and motors*
   Performance Criteria: ISO 14457 for 'Drop Test' for 'Hand Held Equipment'
   Performance Criteria Source: FDA-recognized version of ISO 14457
   Submission Information: Test Report Form per ISO 14457 and DOC

2. **Test name:** Noise Level
   Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
   Performance Criteria: The A-weighted sound pressure value generated by the handpiece and motor or by the high-speed air turbine handpiece should not exceed 80 dB.
   Performance Criteria Source: FDA-recognized version of ISO 14457
   Additional Considerations: The test applies to each handpiece and motor as a system in actual use (i.e., each handpiece used with its respective drive motor).

[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.

Submission Information Test Report Form per ISO 14457 and DOC

3. **Test name:** Surfaces
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: ISO 14457 for 'Surfaces'
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

4. **Test name:** Air-powered handpieces and motors
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: Air-powered handpieces and motors should be operated by a pressurized air supply in accordance with your instructions. The flow rate should be < 80 NL/min at a pressure of 300 ± 100 kPa [3.0 ± 1.0 bar].
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

5. **Test name:** Water Supply (if applicable)
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: The handpiece, if applicable, should provide a coolant capability to the working end of the instrument at a flow rate of at least 50 mL/min at 200 kPa (2.0 bar). The motor, if applicable, should provide water to a handpiece at a flow rate of at least 50 mL/min at 250 kPa (2.5 bar).
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

6. **Test name:** Handpiece cooling air provided by the motor (if applicable)
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: If the motor is equipped with an air-cooling system in accordance with FDA-recognized version of ISO 3964 *Dentistry – Coupling dimensions for handpiece connectors*, then the motor coupling system should be able to transmit a cooling air flow no less than 5 NL/min and no more than 40 NL/min. The recommended pressure range should be 250 kPa to 500 kPa (2.5 bar to 5.0 bar).
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

7. **Test name:** Spray air supply (if applicable)
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: Handpieces having spray air coolant capability should direct air to the working end of the rotary instrument. If water and air are used simultaneously, a cooling mist should be created and transmitted to the working end of the rotary instrument. If spray air functionality is separate from drive air, the handpiece should be

capable of attaining an airflow rate of at least 1.5 NL/min at 200 kPa (2.0 bar). The motor should provide air to a handpiece at a flow rate of at least 1.5 NL/min at 250 kPa (2.5 bar).
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

8. **Test name:** Air and water pressure
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: Applicable motors and handpieces should remain intact, i.e., should not rupture or burst, when subjected to a pressure 50% above your maximum recommended operating pressure.
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

9. **Test name:** Leakage and/or ingress of water
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: ISO 14457 for 'Leakage and/or ingress of water' for 'Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT'
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

10. **Test name:** Operating controls
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: Operating controls should be designed and located to minimize accidental activation. Graphical symbols for operating controls and performance should be in accordance with FDA-recognized version of ISO 9687 *Dentistry – Graphical symbols for dental equipment*. By the use of operating controls, dental motors should be capable of changing speed as you have specified. The controls should be provided at the dental motor itself or at the dental unit. The motor, or motor connected to a dental unit, if applicable, should be provided with operator controls to allow clockwise and anticlockwise rotation, as you have specified. The controls should be provided at the motor itself or at the dental unit.
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

11. **Test name:** Usability
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: Evaluation should be carried out in accordance with FDA-recognized version of IEC 62366-1: *Medical devices — Part 1: Application of usability engineering to medical devices.*
Performance Criteria Source: FDA-recognized version of ISO 14457 (2017)

Submission Information: Test Report Form per ISO 14457 and DOC

12. **Test name:** Connect and supply
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: Handpieces and motors should be capable of being disconnected from and reconnected to interfaces without any special tool.
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

13. **Test name:** Connections for high-speed air turbine handpiece and air motor connectors
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: The configuration, dimensions, and tolerances of connections of the dental handpieces for drive air, exhaust air, spray air, cooling water and fiber-optic light, as appropriate, should be in accordance with FDA-recognized version of ISO 9168 *Dentistry — Hose connectors for air driven dental handpieces*. If the connection of the handpieces and/or motor is made by a quick connector, the connection should be in accordance with your specifications. In addition, if the quick connector is independent from the hose, the quick connector should be in accordance with ISO 9168 *Dentistry – Hose connectors for air driven dental handpieces*.
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

14. **Test name:** Connection for handpieces and motors
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: The configuration, dimensions, and tolerances of the back end of the handpieces and front end of the air motor should comply with FDA-recognized version of ISO 3964 *Dentistry – Coupling dimensions for handpiece connectors*.
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

15. **Test name:** Metallic chuck system
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: Handpieces with metallic chuck systems should be capable of accepting rotary instruments of corresponding mandrels of Type 1, Type 2, Type 3 and Type 4 in ISO 14457 or test mandrel Type 5 as described in ISO 13295 *Dentistry — Mandrels for rotary instruments*. The force needed to extract the test mandrels from the chuck system should meet or exceed the value for the respective type listed below. When locked in the chuck system, test mandrel should transmit a torque that meets or exceeds the value for the respective type listed below without slipping or showing visible signs of destruction.

	Extraction force	Torque
Type 1 to Type 4	≥ 32 N	≥ 0.02N·m
Type 5	≥ 22N	≥ 0.016N·m

Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

16. **Test name:** Test mandrel
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: The test mandrel should have the dimensions shown in the Test Mandrel clause of ISO 14457 (2017). The shape of the shank end for all types of test mandrels should be either conical or rounded to avoid damaging of the chuck system. The mandrel cylindricity should not exceed a value of 2.5 µm and its hardness should exhibit a value of at least 610 HV5. Dimensions without tolerances shown in the Test Mandrel clause of ISO 14457 (2017) should be in accordance with ISO 2768-1 *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications* and ISO 2768-2 *General tolerances — Part 2: Geometrical tolerances for features without individual tolerance indications*.
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

17. **Test name:** Speed
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: The free-running speed of the handpieces and motors should be within ±10% of that specified in your instructions for use.
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

18. **Test name:** Eccentricity
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: The eccentricity of test mandrel Type 4 for high-speed air turbine handpieces without applied load should not exceed a total dynamic eccentricity of 0.03 mm. For test mandrel of types 1, 2 and 4 for straight and angle handpieces in rotation and without applied load should not exceed a total dynamic eccentricity of 0.08 mm.
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

19. **Test name:** Stall torque (if applicable)
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: For high-speed air turbine handpieces, the torque should be at least 0.0005 N·m.

Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

20. **Test name:** Dimensions of the head and nose
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: If you include the head and nose dimensions in the operator's manual, they should be the dimensions as shown in ISO 14457 'Dimensions of the head and nose' and should be expressed to an accuracy of ±0.1 mm of the length or ±1° on angles.
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

21. **Test name:** Output power of high-speed air turbine handpieces (if applicable)
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: If you provide a value for the output power of the handpiece in the instructions for use, you should also provide the supply air pressure, as measured at the inlet to the handpiece, required to produce that power. The measured maximum power output of the handpiece should be at least 90% of the value you provided when tested at the given supply air pressure.
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

22. **Test name:** Handpieces with light (if applicable)
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: The following criteria are applicable for handpieces with any light functionality.

The measured illuminance of the handpiece light should be at least 7,000 lx when operated at the manufacturer's recommended settings.

If a handpiece does not have an internal light source, but does contain elements for light transmission, then the following testing for the efficiency of light transmission should be evaluated. If the elements for light transmission are illuminated on the input side with a light source of no more than 65,000 lx, the light at the output side should be no less than 7,000 lx.
Performance Criteria Source: FDA-recognized version of ISO 14457
Submission Information: Test Report Form per ISO 14457 and DOC

23. **Test name:** Resistance to Reprocessing
Methodology: FDA-recognized version of ISO 14457 *Dentistry – Handpieces and motors*
Performance Criteria: All dental handpieces and motors or parts of dental handpieces and motors should withstand 250 reprocessing cycles without deterioration in

performance. If you recommend a maximum of less than 250 in the instructions, this maximum figure should be used.
Performance Criteria Source: FDA-recognized version of ISO 14457
Additional Considerations: Performance tests #1-23 above, as applicable, should be evaluated using devices subjected to reprocessing cycles. If you provide a rationale for a lower number of permitted reprocessing cycles, then this should be used in place of the 250 cycles stated above.
Submission Information: Test Report Form per ISO 14457 and DOC

Reprocessing Validation

25. **Test name:** Reprocessing (End-user cleaned, and sterilized)
Methodology: FDA recognized version of the following consensus standards (as applicable):
    - ISO 17664-1: *Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices*
    - ISO 17664-2*: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices*
    - AAMI/ANSI ST 79: *Comprehensive guidance to steam sterilization and sterility assurance in health care facilities*
    - AAMI/ANSI ST 98: *Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices*
    - AAMI TIR 12: *Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers*

    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 components and accessories. You should provide a description of the legally marketed sterilization pouch used to sterilize your device and each component of the device.
    Performance Criteria Source: FDA guidance Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff (referred to as the FDA Reprocessing Guidance)
    Submission Information: See Section X.A of the FDA Reprocessing Guidance. The full cleaning and reprocessing validation reports should be provided in the submission and should clearly identify the following information within the submission:

    a. Reprocessing risk assessment for each component of the device.
    b. Spaulding classification for each component or accessory.
    c. Identification and justification for selection of worst-case inoculation locations on the dental handpiece.
    d. Test soil: which should include synthetic blood, bone, bacterial, saliva and mucus.
    e. Rationale for selection of test soils.

f. Separate validated cleaning instructions and separate validated sterilization instructions should be provided. As described in the FDA Reprocessing Guidance document, two quantitative evaluation methods should be used to demonstrate effective cleaning of the subject device. The validation testing should be conducted as described in the FDA Reprocessing Guidance.
g. You should use applicable steam sterilization validation parameters as described in Appendix C of the FDA Reprocessing Guidance.
h. Reprocessing instructions should be clear, complete and include recommended cleaning agents available in the US.

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 the devices covered by this guidance to be categorized as Surface Devices in contact with mucosal membranes with a less than 24 hours contact duration and you should assess the endpoints below per Attachment A of the FDA Biocompatibility Guidance.

- Cytotoxicity
- Sensitization
- Oral Mucous 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 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 determine that testing is needed to address some or all 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, as discussed in 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.

26. **Test name:** Biocompatibility endpoints (identified from the 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/indirect 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