

Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments

Document issued on: May 12, 2004

The draft of this document was issued on May 14, 2002

This document supersedes

- Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA issued May 14, 2002
- Overview of Information Necessary for Premarket Notification Submissions for Endosseous Implants; Final, 04/21/1999
- Information Necessary for Premarket Notification Submissions For Screw-Type Endosseous Implants, 12/09/1996
- Guidance For the Arrangement and Content of a Premarket Approval (PMA) Application for An Endosseous Implant For Prosthetic Attachment, 5/16/89
- (parts of) Calcium Phosphate(Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants, 2/21/97

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Dental Device Branch
Division of Anesthesiology, Infection Control, General Hospital, and Dental Devices
Office of Device Evaluation**

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to <http://www.fda.gov/dockets/ecomments>. When submitting comments, please refer to **Docket No. 02D-0113**. 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 Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

This guidance document was developed as a special control guidance to support the reclassification of the root-form endosseous dental implant device into class II and the reclassification of the endosseous dental implant abutment device into class II. FDA is issuing this guidance in conjunction with a Federal Register notice announcing the final rule reclassifying these device types. Blade-form endosseous dental implants will remain in class III and are not within the scope of this guidance.

Root-form endosseous dental implant devices are characterized by four geometrically distinct types: basket, screw, solid cylinder, and hollow cylinder. The root-form endosseous dental implant device refers to the fixture that is surgically implanted into the patient's bone. The root-form endosseous dental implant device is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore the patient's chewing function.

The endosseous dental implant abutment device is intended to be used with the root-form endosseous dental implant to aid in prosthetic rehabilitation. After the root-form endosseous dental implant is surgically placed and has healed, the endosseous dental implant abutment device is permanently attached to it in a second surgical procedure. The endosseous dental implant abutment extends above the gum, i.e., it is the transgingival component, which serves as the support for the artificial tooth or other prosthetic. However, if the endosseous dental implant includes an integral transgingival component, it does not need to be used with an abutment.

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Following the effective date of the final rule reclassifying these devices, any firm submitting a 510(k) for a root-form endosseous dental implant device or endosseous dental implant abutment device will need to address the issues covered in this special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA's guidance documents, including this guidance, 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.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the guidance, **A Suggested Approach to Resolving Least Burdensome Issues**, <http://www.fda.gov/cdrh/modact/leastburdensome.html>

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of a root-form endosseous dental implant or endosseous dental implant abutment device. Thus, a manufacturer who intends to market a device of either of these generic types should (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807, Subpart E, (2) address the specific risks to health associated with root-form endosseous dental implant or endosseous dental implant abutment devices identified in this guidance, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device.

This special control guidance document identifies the classification regulations and product codes for root-form endosseous dental implants and endosseous dental implant abutment devices (Please refer to section **4. Scope**). In addition, other sections of this special control guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these devices and lead to a timely premarket notification submission (510(k)) review and clearance. This document supplements other FDA documents regarding the content requirements of a 510(k). You should also refer to 21 CFR 807.87 and **How to Prepare a 510(k) Submission** in CDRH's Device Advice at <http://www.fda.gov/cdrh/devadvice/314.html>.

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As described in the guidance entitled, **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**, <http://www.fda.gov/cdrh/ode/parad510.html>, a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once FDA issues a class II special controls guidance document for that device. Additionally, manufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this special control guidance document was used during the device development and testing and should identify the methods or tests used. The report should also include a summary of the test data or a description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 21 CFR 807.87, as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this special controls guidance document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Please refer to section **15. Labeling** for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Summary report

We recommend that the summary report¹ contain the following.

Description of the device and its intended use

¹ A Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED document) that contains the information we recommend in this guidance may suffice in place of the summary report. Please refer to **Announcement of a Pilot Program for Device Submissions (The STED Initiative)** <http://www.fda.gov/cdrh/international/sted.html>.

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We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Please refer to section **5. Device Description** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an “indications for use” enclosure.²

Description of device design requirements

We recommend that you include a brief description of the device design requirements.

Identification of the risk analysis method

We recommend that you identify the risk analysis method(s) you used to assess the risk profile in general, as well as the specific device’s design, and the results of this analysis. (Please refer to section **6. Risks to Health** for the risks to health generally associated with the use of these devices that FDA has identified.)

Discussion of the device characteristics

We recommend that you discuss the device characteristics that address the risks identified in this class II special controls guidance document, as well as any additional risks identified in your risk analysis.

Description of the performance aspects

We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in sections **7-12** of this class II special controls guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.³ (See also 21 CFR 820.30, Subpart C - Design Controls under the Quality System Regulation.)

Reliance on standards

² Refer to <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.

³ If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

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If any part of the device design or testing relies on a recognized standard, we recommend that you include either:

- a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed
- a declaration of conformity to the standard.⁴

(Section 514(c)(1)(B) of the Act). This means that testing must be completed before you submit a declaration of conformity to a recognized standard. For more information, refer to the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/1131.html>.

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you may submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions, see also **Appendix I. Suggested Format for Test Reports**. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a premarket notification submission for a root-form endosseous dental implant or an endosseous dental implant abutment device.

4. Scope

The scope of this document is limited to the device described below.

FDA identifies the generic endosseous dental implant device in 21 CFR 872.3640, product code DZE, as follows:

21 CFR 872.3640 Endosseous implant.

⁴ See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), <http://www.fda.gov/cdrh/ode/reqrecstand.html>.

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An endosseous implant is a device made of a material such as titanium 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, and to restore the patient's chewing function.

Root-form endosseous dental implant devices are characterized by four geometrically distinct types: basket, screw, solid cylinder, and hollow cylinder. In contrast to root-form endosseous implants, blade form endosseous dental implants are flat and have different surgical requirements. This guidance does not apply to blade form endosseous dental implants, which remain in class III.

FDA identifies the generic endosseous dental implant abutment device, as announced in the final rule in the Federal Register reclassifying these devices issued concurrently with this guidance, in 21 CFR 872.3630, product code NHA, as follows:

21 CFR 872.3630 Endosseous dental implant abutment.

An endosseous dental implant abutment device is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

FDA considers any accessory intended to be directly connected to an endosseous dental implant and placed in the mouth for more than 1 hour to be an abutment within the identification set forth in 21 CFR 872.3630. However, temporary accessories used with endosseous dental implants, i.e., accessories that contact tissue for less than 1 hour, are exempt from 510(k) requirements. 21 CFR 872.3980.

5. Device Description

We recommend that you include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. We also recommend that you include a description of device features, with dimensions and tolerances. Examples of features include anti-rotational features, such as internal or external hexagonal features, flat axial surface features on implants, fins, threads, or vertical anti-rotation slots.

We recommend that you include drawings showing all dimensions and tolerances. If your drawing labels are not in English or if your drawings are reproduced from manufacturing prints, please translate and re-label them as necessary, and ensure that you use an adequate font size, before you submit your drawings.

In submissions for root-form endosseous dental implants, we recommend that you provide the characteristics of the abutment connection for each type and size of implant in that submission. In submissions for endosseous dental implant abutments, we recommend that you provide the characteristics of the abutment connection for each type and size of abutment in that submission. In all submissions, these characteristics should include platform size and shape, and connection type.

6. Risks to Health

In the tables below, FDA has identified the risks to health generally associated with the use of the root-form endosseous dental implant and endosseous dental implant abutment devices addressed in this document. The measures recommended to mitigate these identified risks are described in the sections of this guidance document as shown in the table below. You should also conduct a risk analysis, before submitting your 510(k), to identify any other risks specific to your device. The 510(k) should describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this guidance document, or have identified risks additional to those in the guidance, you should provide sufficient detail to support the approach you have used to address that risk.

Risks and Mitigation Measures for Root-Form Endosseous Dental Implants

Identified risk	Recommended mitigation measures (guidance section numbers)
Inadequate function or device failure (mobility, loss of integrity)	7, 8, 9, 10
Damage to existing dentition	8, 11, 12
Infection (local and systemic, including bacterial endocarditis)	10, 11, 12, 13
Injury during surgery, perforation (sinus, alveolar plates), post-surgical parathesia	11, 12, 13

The risks to health that are generally associated with the use of endosseous dental implant abutment devices are listed in the table below.

Risks and Mitigation Measures for Endosseous Dental Implant Abutments

Identified risk	Recommended mitigation measures (guidance section numbers)
Inadequate function (incompatibility)	9
Device failure(mobility, loss of integrity)	7, 8, 9, 10
Damage to existing dentition	8, 9, 11, 12

Root-form endosseous dental implant and endosseous dental implant abutment devices include parts that have permanent contact with tissue/bone and blood. We recommend that you evaluate the biocompatibility of the materials in these parts as described in the **International Standard Organization (ISO) standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing**. Generally, when it is more appropriate to test restorative materials and

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cements after curing, we recommend that you evaluate these materials as described in **ISO 7405:1997 Dentistry - Preclinical Evaluation of Biocompatibility of Medical Devices Used in Dentistry - Test Methods for Dental Materials**. We also recommend that you document the results in your design history file as a part of the Quality Systems Requirements (21 CFR 820.30).⁵ You should select tests appropriate for the duration and level of contact with your device. If identical materials are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of performing biocompatibility testing.

7. Material Composition

We recommend that you include the following information for all components:

- the material identity
- the chemical composition of major constituents and anticipated impurities, unless declaring conformance to a materials standard.

Materials addressed by the standards cited in this guidance document are commonly used in endosseous dental implants.

8. Mechanical Properties

Where indicated by the risk analysis, we recommend that you include the following information for the finished device:

- a description of mechanical properties
- the methodology for determining the mechanical properties, if a testing standard was not used.

We recommend that you conduct fatigue testing for devices that:

- consist of angled abutments;
- are implant or abutment designs that are significantly different from predicate devices; or
- have design features or technological characteristics that have not been previously cleared for market.

We recommend that you test the finished device or components that have undergone the same manufacturing processes as a finished device. You should explain how the properties of your device show adequate device performance. We recommend that you follow American Society for Testing and Materials (ASTM) F86-91 Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants for marking the surface of your device during manufacture. We recommend that you follow

⁵ If your device is labeled sterile, we recommend that you follow the guidance for devices intended for contact with intact skin in **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/361.html>.

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ASTM F601-98 Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants for any fluorescent penetrant inspection that is part of your quality assurance.

Some implants do not use a separate abutment component. However, for those that do, we recommend that you test the assembled implant/abutment system. If the implant or abutment is marketed by another manufacturer, you should follow the assembly instructions that manufacturer provides.

We recommend that you set up testing to ensure that the implant or implant/abutment system is subjected to both compressive and shear (lateral) forces, with no lateral constraint occurring. Testing conditions should mimic actual intraoral use as much as possible.

We recommend that you perform testing of angled abutments at the greatest angulation intended (i.e., the worst case scenario). Abutment angulation greater than 30° should be supported by clinical data. The test setup should clamp the implant so that the implant's long axis makes a 30° angle with the loading direction of the testing machine, unless you are testing an angled abutment of greater than 20°. For angled abutments, the test setup should leave at least 10° of the angulation uncorrected (i.e., a 30° abutment should be tested with the implants long axis at 40° and a 25° abutment should be tested with the implants long axis at 35°). The implant should be supported 3mm below the anticipated crestal bone level, simulating 3mm of bone resorption.

For endosseous dental implants that include materials in which corrosion fatigue has been reported or is expected to occur, or for systems that include polymeric components, we recommend that you perform fatigue testing in water, in normal saline or in a physiological medium at 37°C, at 2 Hz frequency. You should determine the maximum load (endurance limit) your device can withstand for 2×10^6 cycles. For all other systems, it may be appropriate to perform the test in air at 20°C, at 3-15Hz frequency for 5×10^6 cycles.

We recommend that you begin testing at a load of approximately 80% of the static failure load of your device system and decrease the load until the endurance limit is reached. We recommend that you test two (preferably three) specimens to failure at each load, and three specimens at the endurance limit. If any of the specimens fail at the expected endurance limit, we recommend that you reduce the load and repeat the tests until a load is reached at which preferably three specimens reach the required number of cycles (2×10^6 or 5×10^6 , depending on the test medium). We recommend that you test 4 or more loads and 12 or more specimens.

We recommend that you identify the critical failure point and the location of failure initiation on the device component that fails. Failure is defined as material yielding, deformation, or fracture. We recommend that you compare testing results observed for the claimed predicate device(s). You should include a graph of the load versus number of cycles curve along with testing results and data presented in tabular form.

You may use an alternate approach to the load versus number of cycles curve. This may allow the use of fewer samples. One approach is to select a load that is 10% below the static failure load of the

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device system. We recommend testing 5 or more samples at the selected load. All samples should withstand 5 million cycles. If any samples fail, we recommend that you test 5 additional samples at a slightly lower load. If you use this alternate approach, we recommend that you perform the testing in a simulated physiological solution as described above unless the materials are not subject to corrosion fatigue and there are no plastic components. If you are developing an alternative approach, we recommend that you reference ASTM F1108-97 Standard Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants (UNS R56406).

9. Implant to Abutment Compatibility

Implant to abutment compatibility can be demonstrated during the testing described above in section 8. **Mechanical Properties.** If you identify a legally marketed abutment or implant made by another manufacturer as compatible with your abutment or implant, we recommend that you explain how you determined that compatibility and ensured that your tolerances will allow your device to be compatible. If you cannot 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 describe the performance testing that you conducted and the results that establish implant to abutment compatibility.⁶

10. Corrosion Testing

We recommend that you conduct corrosion testing when the implant system includes components fabricated from dissimilar metals that have not been used together before in similar applications. You should perform this testing in a simulated physiological solution at 37°C. Passivated (i.e., finished device condition) and nonpassivated metal surfaces should be evaluated. We recommend that testing assess:

- corrosion potential of each metal or alloy;
- couple potential for the assembled dissimilar metal implant system; and
- corrosion rate for the assembled dissimilar metal implant system.

For one example of a test method for pitting or crevice corrosion, please see ASTM F746-87(1994) Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials.

11. Modified Surfaces Information

We recommend that you describe the implant surface characteristics if the surface is modified or has properties claimed to facilitate bone deposition. You should include information on the nature of, and

⁶ After your device has been cleared, if you revise your labeling to identify additional legally marketed abutments or implants as compatible, we recommend that you document how you determined compatibility and ensured that your tolerances will allow your device to be compatible. If you cannot establish implant to abutment compatibility based solely on descriptive information, you should document the performance testing conducted and the results obtained that establish compatibility in your design history file as a part of the Quality Systems Requirements (21 CFR 820.30).

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processes by which, surfaces are modified such as coatings, blasted surfaces, etched surfaces, or other surface treatments that are applied.

If the modified surface is significantly different from predicate devices, we recommend that you provide the information described below.

Ceramic Coating Information

We recommend that you include the information listed below for an implant coated with a ceramic coating such as hydroxyapatite or calcium phosphate.

- particle size and particle size distribution of the powder used for the coating
- average porosity size for the coating
- overall pore volume for the coating
- identity of the area of the implant to be coated
- scanning electron microscopy pictures at 100X of the coated implant surfaces and of a cross-sectioned area of the device showing the coating interface
- measurements of coating thickness and tolerances
- chemical analysis of the powder before and after coating, including Ca/P ratios in atomic percent and elemental analysis
- total percentage of all crystalline phases in the coating and total percentage of crystalline hydroxyapatite in the coating
- type of deposition process used and the post-deposition treatment
- x-ray diffraction pattern of the powder and the coating in terms of relative intensity versus diffraction angle
- surface roughness of the coating
- abrasion characteristics of the coating, including the abrasion testing methodology.

We also recommend that you include static tensile and shear bonding strengths between the coating and the implant surface with testing from 5 or more samples included in the averages. We recommend the following standards, where appropriate to your device's composition:

- ASTM F1160-98 Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical Coatings
- ASTM F1147-99 Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings
- ASTM F1501-95 Standard Test Method for Tension Testing of Calcium Phosphate Coatings

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- ASTM F1658-95 Standard Test Method for Shear Testing of Calcium Phosphate
- ASTM F1659-95 Standard Test Method for Bending and Shear Testing of Calcium Phosphate Coatings on Solid Metallic Substrates

For CA phosphate coatings please see ASTM F1609-95 Standard Specification for Calcium Phosphate Coatings for Implantable Materials. For other types of ceramic coatings, ASTM F1501-95 Standard Test Method for Tension Testing of Calcium Phosphate Coatings may be useful in devising your own test method.

Metallic Coating Information

We recommend that you include the information listed below for an implant coated with a metallic coating:

- complete chemical composition of the powder used for the coating and of the coating itself
- coating thickness and porosity
- mean volume percent of voids
- surface roughness of the coating
- identity of the area of the implant to be coated
- scanning electron microscopy pictures at 100X of the coated implant surfaces and of a cross-sectioned area of the device showing the coating interface
- abrasion characteristics of the coating, including the abrasion testing methodology.

We also recommend that you include static tensile and shear bonding strengths of the coating to the implant with results from 5 or more samples included in the averages. We recommend the following standards, where appropriate to your device's composition:

- ASTM F1044-95 Standard Test Method for Shear Testing of Porous Metal Coatings
- ASTM F1147-99 Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings
- ASTM F1160-98 Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical Coatings
- ASTM F1580-95 Standard Specification for Titanium and Titanium-6% Aluminum-4% Vanadium Alloy Powders for Coating Surgical Implants.

Blasted Surfaces Information

We recommend that you include the information listed below for an implant with a blasted surface:

- identity of any surface treatments that blast the implant
- composition of the particles

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- identity of any treatments to remove particles from implant surfaces
- identity of agents used in particle removal
- chemical analysis of the surface to verify that any chemicals used to remove particles have been washed from the surface
- photomicrographs of blasted surfaces to show whether or not there are particles remaining behind on the surface.

12. Clinical Studies

In accordance with the least burdensome provisions of the FDA Modernization Act of 1997, the agency will rely on well-designed bench and/or animal testing rather than requiring clinical studies for new devices unless there is a specific justification for asking for clinical information to support a determination of substantial equivalence. While, in general, clinical studies will not be needed for most implant or abutment devices, FDA may recommend that you collect clinical data for devices with any one of the following characteristics:

- material formulations or designs dissimilar from material formulations or designs previously cleared under a premarket notification
- lengths less than 7 mm and/or implant diameters less than 3.25 mm
- an angulation of the accompanying or recommended implant abutment greater than 30°
- new technology, i.e., technology different from that used in a legally marketed implant or abutment
- indications for use dissimilar from devices of the same type.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. The Dental Devices Branch is available to discuss any questions you may have.

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, the study must be conducted in accordance with the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812. FDA believes this device is a significant risk device as defined in 21 CFR 812.3(m)(4) and, therefore, studies involving these devices do not qualify for the abbreviated IDE requirements of 21 CFR 812.2(b). In addition to the requirement of having an FDA-approved IDE, sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

Clinical investigation ordinarily should include a randomized, well-controlled clinical trial designed to demonstrate the substantial equivalence of the device when used as described in the Indications for Use statement. It may be possible to use historical controls when the hypotheses are the same and the protocols are similar. For statistical purposes, the study should demonstrate the device is substantially equivalent to, or not inferior to the performance of legally marketed predicate devices of this type. Each

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study arm should have a statistically valid number of patients. We recommend that you consult a statistician familiar with medical device studies.

FDA recommends that you conduct any clinical evaluations of implants and abutments for three years with the implant under loaded conditions. Results should include such information as implant mobility, infections, broken implants or abutments, adverse events, and should also include a detailed explanation for all patients lost to follow-up. Results derived from these investigations should meet the definition of valid scientific data as defined in 21 CFR 860.7. The studies should be conducted by investigators experienced in implant dentistry, clinical research design, and data analysis.

Inclusion and Exclusion Criteria

We recommend that you define the inclusion and exclusion criteria in your clinical study protocol. We recommend that you describe and explain any deviations from your inclusion and exclusion criteria. We also recommend that you describe the study population in terms of the distribution of the variables, if relevant to study outcome, listed below:

- intended use of the device
- number of patients in experimental and control groups
- age and gender distribution of the patients in the experimental and control groups
- status of dentition (dentate vs. edentulous, minimum number of teeth and maxillomandibular jaw relationships)
- occlusal scheme (i.e., cross bites, tilted teeth, teeth in buccoversion/labioversion)
- minimal ridge dimensions and quality of bone (Type I-IV⁷), if part of the protocol
- applicable prosthetic variables, such as restorative materials, permissible abutment angulation, and length of span for implant supported bridges.

Pre-implantation Assessment

The pre-implant assessment described in your study protocol should include:

- description of the general health of the patient, identifying any medical conditions that may affect the outcome of the study
- description of the patient's dental status that may affect the outcome of the study
- location of the intended site(s) for implantation
- description of special conditions for which the implant is to be used (e.g., Type IV bone, for maxillary sinus areas),
- description of pathological conditions (e.g., infection, bleeding, inflammation)
- condition of the opposing teeth and type of occlusion

⁷ Misch, CE. Contemporary Implant Dentistry. St. Louis, Missouri: Mosby, 1999; pp 89-118.

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- identification of patients who brux or clench
- oral hygiene regimen to be used around the implant based on instructions in the labeling
- density of bone at the implant site (i.e., Type I to Type IV bone).

The pre-implant assessment described in your study protocol should also include standardized radiographs to quantify the ridge height and width of the supporting bone and locate major anatomical features. Radiographs taken over the study period should be readily comparable. You should also use this procedure in the post-implant assessments. Examples of appropriate radiographs are:

- periapical or panoramic radiographs
- extraoral radiographs
- cephalometric radiographs
- Computed Axial Tomography (CAT) scans.

Post-implant Assessment

The post-implant assessment described in your study protocol should include the information discussed below.

Clinical and Radiographic Assessment Frequency

We recommend that you specify how frequently clinical and radiographic assessment will occur. Postsurgical intervals that have been reported in the dental literature are generally acceptable. Examples of these intervals are weekly for the first month, 3 months, 6 months, 12 months, 2 years, and 3 years. Minor deviations from this sequence should not conflict with the protocol. Abbreviated evaluation intervals or significant deviations from these parameters should be justified on the basis of wound healing parameters.

Interval Between Implantation Stage

We recommend that you specify the time interval between each stage of the implantation (i.e., the time between implant placement and uncovering for abutment placement and time between implant placement and occlusal loading). The 3-year follow-up period should be measured from the time the implant is subject to occlusal forces. You should describe the occlusal loading parameters and variations permissible within the protocol.

Medications During the Study

We recommend that you identify any medications and the amounts taken during the clinical study that might affect study outcomes. Medications such as antibiotics, analgesics, and topical rinses are examples of medications that you should record. Use of antibiotics, analgesics, and topical rinses should be standardized as much as possible.

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Radiographs

We recommend that you obtain radiographs as described in the study protocol. Radiographs may not be required at each post-implant assessment. You should quantify the amount of alveolar ridge resorption based on radiographs. You should also document any radiographic evidence of periapical radiolucency.

The post-implant assessment described in your study protocol should also record the following clinical parameters and observations during each evaluation, where appropriate.

Gingival Health

We recommend that you specify the gingival and inflammatory indices used.

Tooth and Implant Mobility

We recommend that you specify method of evaluation and type of classification used.

Pocket Probing Depth

We recommend that you use the same type of probe and probing technique at each evaluation. The clinician's technique should be calibrated with respect to force used as well as probe angulation. The use of stents, wherever practical, may improve intra- as well as inter-examiner reliability.

Clinical Attachment Level

We recommend that you use a standardized technique, as well as examiner calibration, for this measuring the clinical attachment level.

Postoperative Complications

We recommend that you record any postoperative complications encountered, and the times at which they occurred. These should include, but need not be limited to the post-operative complications listed below:

- anesthesia or paresthesia, temporary or permanent
- mandibular fracture
- significant loss of alveolar ridge height, as specified in the protocol
- osteomyelitis, oral-antral, or oral-nasal fistula
- adjacent teeth adversely affected by implant placement
- abnormal or prolonged pain after insertion as described in protocol
- infection related to implant placement
- failure to maintain adequate oral hygiene.

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If it is necessary to retrieve any implant during follow up, we recommend that you follow ASTM F561-97 Practice for Retrieval and Analysis of Implanted Medical Devices, and Associated Tissues.

Adverse reactions and complications

We recommend that you describe and tabulate each adverse reaction and complication. These should include the events listed below:

- infection
- implant loss prior to loading
- implant breakage
- loss of loaded implants
- pain
- altered sensation
- temporomandibular joint problems

We recommend that you provide the number of patients discontinued, the rationale for discontinuation, and the time of discontinuation. Under Adverse Events, you should provide a detailed and complete failure analysis report for each device failure.

Data Tabulation

We recommend that you provide a tabulation of data from all individual subject report forms. You should include copies of subject report forms for each subject who did not complete the investigation, if possible. You should also include a summary table showing the duration of follow-up for each subject in the investigation.

Statistical Analyses

We recommend that you provide the results of statistical analyses from the clinical investigations. These results should include statistical methodology and rationale for each statistical test. You should cite references or submit formulas for each methodology, as well as an explanation of any deviations from the methodology. Analysis of statistical data should show the rate of success, failure, and complications. The time-specific cumulative failure rate and complication rate should be calculated by statistical survival analysis. You should include a lifetable analysis.

Additional Clinical Study Information

We recommend that you include articles published in peer reviewed journals, containing information on the device in the 510(k) relevant to the clinical study (i.e., for the same indication, or uses of the implant in a clinical study).

We recommend that your clinical study protocol include a statement regarding study progress at the time you submit your 510(k), stating whether the study is completed, in long term follow-up, or

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enrolling patients. You should also include a statement about how clearance of the 510(k) will change the status of the study.

We recommend that you include in the clinical protocol any methods not previously mentioned that are used to eliminate bias on the part of the subjects or investigators.

13. Labeling

The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR 807.87(e).⁸

Professional Labeling

As a prescription device, root-form endosseous dental implant and endosseous dental implant abutment devices are exempt from needing adequate directions for lay use. Nevertheless, under 21 CFR 807.87(e), instructions should be clear and concise and delineate the technological features of the specific device and how the device should be used in patients. We recommend that you provide users with a surgical manual along with the instructions for use. Professional labeling should contain detailed instructions, particularly for those sections of the surgical or restoration procedures where the device differs from other endosseous dental implant systems. You should provide all relevant precautions and warnings in the professional labeling. If there are any precautions or warnings that relate to unpackaging or sterility, we recommend that you repeat precautions or warnings on the package labels.

Sterilization Instructions

If any parts are provided non-sterile, i.e., to be sterilized before use, we recommend that you provide sterilization instructions.

Patient Labeling

If patient labeling is appropriate, we recommend that you follow **Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers**, <http://www.fda.gov/cdrh/ohip/guidance/1128.html> in preparing patient labeling.

⁸ Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a device is introduced into interstate commerce. In addition, final labeling for prescription devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.

Appendix I Suggested Format for Test Reports

If you choose to submit a traditional 510(k) or if you use test methods not given in the standards cited in this guidance, you should submit test reports. These test reports should include the following elements, or an explanation for their omission:

- reference to the test method or summary of your test protocol
- methods for sample preparation
- drawing of your test set up
- failure report
- identification of the failure regions and a justification of risk if the region falls in an area which would require surgical removal of the implant
- acceptance criteria for each test, unless specifications are included in the recognized standard.

If the test was conducted in conformance with a recognized standard, you need not describe the details of the test method.