Contains Nonbinding Recommendations

Draft – Not for Implementation

Premarket Notification (510(k)) Submissions for Bone Anchors

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on January 3, 2017.

This guidance is a reissuance of the April 20, 1996 "Guidance Document for Testing Bone Anchor Devices" with updated content.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact the Division of Orthopedic Devices at (301) 796-5650.

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

Preface

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Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1400005 to identify the guidance you are requesting.

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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This draft guidance document provides recommendations for 510(k) submissions for bone anchor (suture anchor) devices. These devices are indicated for attachment of soft tissue to bone. This guidance is issued for comment purposes only.

This draft guidance is a reissuance of the prior draft guidance "Guidance Document for Testing Bone Anchor Devices" dated April 20, 1996. FDA is updating this guidance to clarify and provide current thinking on the recommended content for a bone anchor 510(k) submission, including performance testing recommendations and device description. Specifically, this guidance reflects the most current thinking on relevant bench testing methods for bone anchor devices including nitinol and absorbable polymeric bone anchors.

For the current edition of the FDA-recognized standards referenced in this document, see the FDA Recognized Consensus Standards Database Web site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

FDA's guidance documents, including this draft 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.

II. Scope

This guidance document is intended to address the relevant descriptive characteristics, labeling, biocompatibility, and bench testing related to the pre-market notification (510(k)) review of bone anchor (suture anchor) devices used in the appendicular skeleton for attachment of soft tissue to bone. This attachment may be achieved by attaching one end of a suture to the soft tissue and the other end to a device that is inserted into the bone. This document does not address anchors used to attach bone to bone, or interference screw components, nor does it address anchors intended for use with artificial ligaments or tendons.

These devices are classified under 21 CFR 888.3030 and 21 CFR 888.3040 and with the product codes listed in the table below:

Product Code	**Regulation Number**	**Name**
MAI	21 CFR 888.3030	Fastener, fixation, biodegradable, soft tissue
MBI	21 CFR 888.3040	Fastener, fixation, nondegradable, soft tissue

Please note that suture anchor devices may have historically been cleared with other product codes (e.g., HWC); however, these product codes are more appropriate for other orthopedic devices (e.g., fixation screws). To ensure that the product code clearly reflects the intended device type (i.e., bone anchor), we recommend that future submissions be submitted and cleared under the product codes MAI or MBI, as noted above.

III. 510(k) Submission Recommendations

A. Device Description

We recommend you identify your device by the applicable regulation number and product code indicated in Section II above and include the information described below.

1. General Suture Anchors

a. Bone anchor dimensions (e.g., length, inner/outer diameter) and material (including applicable material standards, if any) should be provided. We recommend you provide fully dimensioned engineering drawings for all device components to capture this information.

b. If there are multiple bone anchor components (e.g., an inner component and outer sleeve), you should provide a description of how the components are assembled.

c. If a suture is included with the anchor construct (e.g., preloaded with the anchor on an inserter), you should provide the identity and percentages of all materials (including coatings and additives) and the sizes of sutures using the size system identified in the currently recognized United States Pharmacopoeia (USP). If the suture has been previously cleared by the Agency, you should identify the submission number (e.g., 510(k) number). For more information on appropriate information to be included with a suture component, please refer to the FDA guidance document, "Class II Special Controls Guidance Document: Surgical Sutures" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072701.pdf).

d. A description of the suture/anchor attachment mechanism (e.g., suture tied to an eyelet on the distal end of the anchor) should be provided.

e. Some anchor constructs are intended for use with a suture to be determined by the end user. If the anchor system does not include a suture, but is intended for use with a generic suture of a specific size, you should ensure that the recommended suture size (e.g., USP size 2) and type (i.e., absorbable vs. non-absorbable) is specified in the submission and the draft labeling.

f. If the anchor is intended to be used as part of a system with device-specific instrumentation, a description of all associated instruments (e.g., suture anchor driver) should be provided.

g. You should provide the method of bone preparation for insertion of the anchor (e.g., self-tapping, or pilot hole diameter and depth).

h. All compatible components of the fixation system should be provided.

The recommended descriptive characteristics listed above are meant to cover all suture anchor components. The additional nitinol and absorbable information discussed below should be provided, if applicable, in addition to the general information discussed above.

2. Nitinol Suture Anchors

a. A description of conformance to any applicable material standard (e.g., ASTM F2063: *Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants*) should be provided.

b. If there are no applicable standards for your material, you should provide the chemical composition. You should also describe the mode of action (e.g., thermal shape memory or superelasticity) by which the suture anchor transitions to the specified size and shape.

c. The transition temperatures (i.e., A_s and A_f) of your final, finished device using samples from multiple production lots should be provided. We recommend using the methods described in ASTM F2004: *Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis*, ASTM F2082: *Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery*, or an equivalent method. You should provide specifications for the acceptable A_f temperature range for your suture anchor.

d. You should provide a description of the final processing, including surface treatment processes (e.g., shape setting, polishing, and/or passivation steps) performed on your nitinol suture anchor (including any electro-polishing and/or passivation steps).

3. Polymeric Absorbable Suture Anchors

a. The material of construction and any applicable consensus standards to which it conforms should be provided. If the identical material was used in a predicate anchor, you should specify the 510(k) number for this predicate.

b. A description of the as-manufactured analytical properties of your device (e.g., molecular weight, residual monomer content, and crystallinity) should be provided.

c. The degradation mechanism (e.g., hydrolysis) should be provided.

d. The degradation timeframe should be provided.

If the materials of construction or processing are not identical to a predicate device, and you are relying on a risk assessment in lieu of new testing to address materials concerns such as biocompatibility, you should also provide the following information:

a. Specifications for the incoming raw material.

b. A description of the processing (including sterilization) used to create the final device.

As of the date of this draft guidance, the only cleared absorbable suture anchor components consist of hydrolytically degradable polymers (e.g., PLLA). Suture anchors that consist of other material types, or with another mechanism of degradation, would likely require additional types of information.

B. Predicate Comparison

The 510(k) must include a comparison of the proposed device to a legally marketed predicate device[1] (including the 510(k) number, if available) and provide information to show how your device is similar to, and different from, the predicate in terms of indications for use and technological characteristics (e.g., material, geometry). Side by side comparisons, whenever possible, are desirable, for example, using a tabular format as shown below. This table is not intended to represent an exhaustive list of comparative parameters; you should ensure you provide all relevant device descriptive characteristics as outlined in the "Device Description" section, above.

Description	Subject Device	Predicate Device (Kxxxxxx)
Indications For Use		
Anchor Geometry		
Anchor Dimensions (inner/outer diameters)		
Anchor Material		
Range of Suture Diameter		
Method of Fixation of Suture to Anchor		
Other Relevant Characteristics		

C. Biocompatibility

Significance: Bone anchors contain patient-contacting materials, which, when used for their intended purpose (i.e., contact type and duration), may induce a harmful biological response.

Recommendation: You should determine the biocompatibility of all patient-contacting materials present in your device (including the anchor and associated suture). If your device is identical in composition and processing to bone anchors with a history of successful use, you may reference previous testing experience or literature, if appropriate. To address the device materials, we recommend you provide a reference to either a recognized consensus standard, or to a Letter of Authorization (LOA) for a device Master File (MAF).

If you are unable to identify a legally marketed predicate device with similar location/duration of contact and intended use that uses the same materials as used in your device, we recommend you conduct and provide a biocompatibility risk assessment. The assessment should explain the relationship between the identified biocompatibility risks, the information available to mitigate the identified risks, and any knowledge gaps that remain. You should then provide any

[1] 21 CFR 807.87(f)

biocompatibility testing or other evaluations that were conducted to mitigate any remaining risks.

We recommend that you follow FDA's guidance "Use of International Standard ISO10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm348890.pdf) which identifies the types of biocompatibility assessments that should be considered and recommendations regarding how to conduct related tests.

Per ISO 10993-1 and Attachment A of FDA's guidance, bone anchors are considered implant devices in contact with tissue/bone for a permanent contact duration. Therefore, the following endpoints should be addressed in your biocompatibility evaluation:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Subchronic toxicity (Sub-acute toxicity)
- Genotoxicity (We recommend that both mutagenicity and clastogenicity be assessed.)
- Implantation
- Chronic Toxicity
- Carcinogenicity

For device-specific, patient-contacting device instrumentation (e.g., inserter shafts) in contact with tissue/bone for a temporary contact duration, the following endpoints should be addressed in your biocompatibility evaluation:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity

The following additional considerations are recommended for bone anchors:

- If the suture component includes a coating, this coating should be evaluated for biocompatibility in addition to the bulk suture material.

- If your biocompatibility assessment relies on the use of raw materials, you should ensure that you address the subsequent processing, cleaning, and sterilization steps to address the biocompatibility of the final sterilized device.

- Differences in formulation, processing, sterilization, or device surface properties (e.g., nanostructuring) that could affect biocompatibility of the final product may warrant additional biocompatibility testing.

- For new formulations of degradable anchors (e.g., new combinations of degradable materials, new additives, etc.), in addition to the testing described above, we recommend you address the biocompatibility of the anchor over the life of the implant (i.e., the time required for healing of the soft tissues being repaired) and discuss the starting, intermediate, and final degradation products present over the course of degradation.

D. Sterility

Significance: Bone anchors are implanted devices, and should be adequately sterilized to minimize infections and related complications.

Recommendation: For bone anchors labeled as sterile, we recommend that you provide information for the finished device in accordance with the guidance, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile" (http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm109897.pdf).

E. Reprocessing (including single-use devices provided non-sterile)

Significance: Many of the patient-contacting components of bone anchor instrumentation are reused, and should be adequately cleaned, disinfected, and sterilized between uses to minimize infections and prevent device degradation.

Recommendation: Under the FDA labeling regulations (21 CFR 801), a device must have adequate directions for use, which include instructions on preparing a device for use. Instructions on how to reprocess a reusable device, or a single-use device that is provided non-sterile to the user, are critical to ensure that a device is appropriately prepared for its initial and subsequent uses. For recommendations regarding the development and validation of reprocessing instructions in your proposed device labeling, please refer to the guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"

(http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf).

F. Pyrogenicity

Significance: Pyrogenicity testing is used to help protect patients from the risk of febrile reaction due to gram-negative bacterial endotoxins and/or chemicals that can leach from a medical device (e.g., material-mediated pyrogens).

Recommendation: To address the risks associated with the presence of bacterial endotoxins, bone anchors should meet pyrogen limit specifications by following the recommendations outlined in the guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile" (http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm109897.pdf). To address the risks associated with material-mediated pyrogens, you should follow the recommendations in the guidance "Use of International Standard ISO10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm348890.pdf).

For devices intended to be labeled as "non-pyrogenic," we recommend that both bacterial endotoxin and rabbit material-mediated pyrogen testing be conducted.

G. Shelf Life and Packaging

Significance: Shelf-life testing is conducted to support the proposed expiration date through evaluation of the package integrity for maintaining device sterility and/or evaluation of any changes to device performance or functionality.

Recommendation: With respect to package integrity for maintaining device sterility, you should provide a description of the packaging, including how it will maintain the device's sterility, and a description of the package integrity test methods used. FDA recommends that package integrity test methods include simulated distribution and associated package integrity, as well as simulated (and/or real-time) aging and associated seal strength testing, to validate package integrity and shelf-life claims. We recommend you follow the methods described in the FDA-recognized series of consensus standards, AAMI/ANSI/ISO 11607: *Packaging for Terminally Sterilized Medical Devices*. Since many absorbable materials will be sensitive to moisture and temperature, we recommend that your packaging description and testing address these important considerations for any absorbable device.

With respect to evaluating the effects of aging on device performance or functionality, shelf-life studies should evaluate the critical physical and mechanical properties of the device that are required to ensure it will perform adequately and consistently during the entire proposed shelf

life. To evaluate device functionality, we recommend that you assess each of the bench tests described below in Section III.I, Non-Clinical Performance Testing, and repeat all tests that evaluate design components or characteristics that may be potentially affected by aging.

We recommend that you provide the protocol(s) used for your shelf-life testing and the conclusions drawn from your results. If you use devices subject to accelerated aging for shelf-life testing, we recommend that you specify the way in which the devices were aged. For devices or components containing polymeric materials, you should plan to conduct testing on real-time aged samples to confirm that the accelerated aging is reflective of real-time aging. This testing may be conducted in parallel with 510(k) review and clearance, with results documented to file in the design history file (i.e., the test reports do not need to be submitted to FDA).

H. Magnetic Resonance (MR) Compatibility

Significance: MR imaging of patients with bone anchors poses the following potential hazards:

- movement of the implant, resulting in tissue damage or misplacement,
- heating of the implant and subsequent tissue damage, and
- image artifacts that may render the MR images uninterpretable or misleading.

Recommendation: We recommend that you address the issues affecting safety and compatibility of your device (including the anchor and associated suture) in the MRI environment as described in FDA's guidance "Establishing Safety and Compatibility of Passive Implants in the MR (Magnetic Resonance) Environment" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107708.pdf).

I. Non-Clinical Performance Testing

FDA recommends that you provide the information below to evaluate the material and performance characteristics of your final, worst-case, sterilized device (including the anchor and associated suture). If suture components are provided sterile and must be industrially resterilized with the suture anchor, you should provide a robust rationale that addresses why the resterilization is not expected to affect the performance of the suture component. Additionally, to allow an evaluation of the implantation procedure and the use of device specific instrumentation, implantation of anchor components in bench testing should be performed according to the surgical technique as identified in the labeling.

While there is no absolute minimum acceptable sample size for testing, a sample size of five (5) units has historically been accepted as the minimum for bench testing. Additional issues in testing (e.g., large variability in results) or device design may indicate that a sample size beyond this minimum is recommended.

It is recommended that all testing include comparison to a predicate with equivalent indications for use to the subject bone anchor system; however, a comparison to worst-case clinical loading on the device may be sufficient to evaluate the performance of a suture anchor and establish equivalence. If a comparison to clinical loading is provided, we recommend that you provide a robust, clinically-based justification of the loads used (including literature citations where relevant).

For each test, you should ensure that a complete test report is provided, including all relevant information (e.g., a description of the test setup, description of test specimens, worst-case rationale for test specimens, pre-specified acceptance criteria, test protocol of sufficient detail to allow an evaluation of the methods used, test results including raw data, test conclusions).

1. Suture Characterization

Significance: Inadequate suture strength can lead to premature failure of the anchor during implantation or clinical use.

Expectation: We expect that you include all appropriate information related to the physical and performance characteristics of the suture as described in FDA's guidance document, "Class II Special Controls Guidance Document: Surgical Sutures" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072701.pdf). If the suture has been previously cleared in a predicate submission, this submission may be referenced in lieu of suture characterization.

2. Insertion Testing

Significance: Insertion into dense bone can cause failure of the bone anchor. An evaluation of worst-case insertion provides assurance of adequate insertion strength of the anchor and associated insertion instrumentation.

Recommendation: Insertion testing should be conducted in the worst-case bone or bone substitute based on the anatomic locations in the indications for use. If a bone substitute is used, we recommend that it conform to ASTM F1839: *Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments*. The worst-case for insertion should evaluate the ability of the anchor to be deployed correctly and without damage to the device. Although this is typically performed in more dense bone, if there is concern that an anchor design may not successfully deploy in less dense bone, this scenario should also be evaluated. Testing should be performed in accordance with the steps described in the surgical technique (e.g., pilot hole preparation).

Example: For bone anchors indicated for use in the hip, we recommend that you provide insertion testing that simulates the hard cortical bone of the hip. While it is the responsibility of the submitter to provide a rationale for an acceptable test setup,

the Agency recommends testing in a dense bone substitute (e.g., 50 pound per cubic foot (PCF) foam per ASTM F1839). If another test setup is used to evaluate the insertion of anchors with hip indications, you should provide a rationale for the acceptability of the insertion construct.

3. Pullout Testing

Significance: Bone anchors subjected to a tensile load may fail by pullout from the bone or breakage of the anchor or suture.

Recommendation: Pullout testing should be conducted in the worst-case bone or bone substitute based on the anatomic locations of the indications for use. Note that the failure point of the bone anchor may be the suture itself, the suture/anchor interface, or the anchor/bone interface. The prevalence of these various failure modes may be affected by the density of the test substrate. Although there is no single accepted value for testing, we recommend testing at a middle range of density (e.g., 20 PCF per ASTM F1839); however, this density may not be appropriate for all designs and indications. We recommend you provide a robust rationale as to your choice of bone or bone substitute based on the indications for use and technological characteristics (i.e., likely failure modes) of the bone anchor. For certain suture anchor designs, testing in ambient air may be appropriate; however, some devices (e.g., nitinol) may be affected by testing conditions (e.g., testing temperature, testing immersed in saline), so it is recommended that the test setup take these factors into account when appropriate.

4. Component Interconnection Testing

Significance: Bone anchors can be assembled from multiple components that may fail in a different manner than insertion or pullout.

Recommendation: If a bone anchor is assembled from multiple components (e.g., two pieces that are screwed together), interconnection strength between components should be evaluated and compared against worst-case expected loading or a legally marketed predicate device.

5. Fatigue Testing

Significance: Bone anchor components subjected to cyclic loading may experience failure of the anchor construct due to suture fray or fatigue failure of the anchor component.

Recommendation: If the anchor is expected to experience cyclic loading (i.e., healing time exceeds the time the anatomic location is immobilized post-surgically), it is recommended that you conduct fatigue testing to address the concern of bone anchor fixation failure. We recommend that you provide a robust clinical rationale (e.g., clinical literature) to support a decision that fatigue testing is not necessary for the specific indications. Additionally, if the anchor design is novel

and may present a new worst-case for cyclic failure (e.g., presence of a new stress riser at the suture connection point), fatigue testing is recommended regardless of the expected healing time.

We recommend that you conduct cyclic testing with a clinically justified load and cycle number. We further recommend you conduct pullout testing following cyclic loading to demonstrate that pullout strength is retained.

6. Corrosion (Nitinol)

Significance: Nitinol, or other metallic bone anchor materials, may experience surface corrosion and subsequent release of ions due to electrochemical interactions occurring in the body.

Recommendation: An evaluation of the breakdown pitting corrosion potential of your suture anchor should be provided. It is recommended that this evaluation be performed according to ASTM F2129**:** *Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices*. In this evaluation, we recommend you address the following:

- Test devices should be representative of final sterilized devices and selected such that potential variations due to manufacturing can be assessed (e.g., testing samples from multiple lots).

- The worst-case implant component should be used to assess corrosion resistance. Considerations should be given to factors such as geometry or size that may affect surface finishing such as adequate polishing of regions of high curvature.

- Test reports for pitting corrosion potential testing should be consistent with ASTM F2129. For example, test reports should include corrosion/rest potentials, breakdown potentials, as well as polarization curves. When practical, we recommend that you plot all polarization curves in one graph. You should ensure that you discuss any deviations from the ASTM F2129 standard (e.g., test setup not meeting the criteria outlined in ASTM G5: *Standard Reference Test Method for Making Potentiodynamic Anodic Polarization Measurements*).

- Results should be assessed against your acceptance criteria. The acceptance criteria for the pitting corrosion testing should be determined by comparison to a legally marketed predicate device with good clinical history of use (i.e., no history of corrosion-related fractures or adverse events associated with nickel release). Alternatively, while there is a paucity of data directly linking *in vitro* corrosion testing to *in vivo* corrosion outcomes, conservative guidelines have

been published by Corbett (2004)[2], which may also be used to establish acceptance criteria.

- If breakdown occurred, you should include results of the visual inspection of your device before and after testing to assess evidence of pitting. Images of sufficient magnification should be included to support these observations and identify pit locations.

Based on the device design, pitting corrosion evaluation, and surface finishing information, further corrosion testing (e.g., metal ion release) and/or surface characterization analyses may be recommended.

7. Degradation Testing

Significance: Anchors composed of degradable polymers lose their structural and mechanical properties over time as they degrade, which may lead to insufficient mechanical properties if degradation occurs too rapidly.

Recommendation: We recommend providing an evaluation of the degradation of anchor components, consistent with the methods outlined in:

ASTM F1635: *Standard Test Method for in vitro Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants*

and

ASTM F2502: *Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants.*

We recommend that you apply an appropriately justified load to the anchor during testing. Furthermore, it is recommended that degradation testing be performed in an appropriate worst-case bone substitute consistent with the setup described in the pullout testing section above.

Also, we recommend that the worst-case implant component configuration(s) be used to address degradation of mechanical properties. Multiple factors may affect the rate of degradation, including surface area to volume ratio, location of critical design features, etc., and the worst case component may not be intuitive (i.e., may not be the smallest component size). A justification for the applied loading and worst-case component(s) selected should be provided.

[2] Corbett, R.A. "Laboratory Corrosion Testing of Medical Implants" In: Shrivastava S, editor. Proc. Materials and Processes for Medical Devices Conf., Materials Park, OH: ASM International; 2004. p. 166-171.

Bone anchors should be tested to at least twice the expected duration of healing. During testing, the peak pullout force should be compared to a legally marketed predicate with equivalent indications for use and technological characteristics. We recommend you compare the performance at time zero (0) and at multiple time points beyond (e.g., 3, 6, 12, 26 weeks). We further recommend that your test report for mechanical properties over time include the force-displacement curves acquired at each time point and a description of the failure mode observed.

In addition to the mechanical characterization, it is recommended that you characterize material degradation (e.g., mass loss, molecular weight changes (number and weight average)) over the course of testing to more fully characterize the degradation process. You should provide a detailed description of the methods used along with references to any applicable consensus standards followed.

J. Clinical Performance Testing

Clinical evidence is generally unnecessary for most bone anchors; however, such testing may be requested in situations such as the following:

- indications for use dissimilar from legally marketed devices of the same type that would not constitute a new intended use,
- different technology (e.g., materials) from that used in legally marketed devices of the same type, yet does not raise different questions of safety or effectiveness,
- cases where engineering and/or animal testing raises issues that warrant further evaluation with clinical evidence, and/or
- devices with lower mechanical properties (e.g., pullout strength) than predicates.

FDA will consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. 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 under the Investigational Device Exemptions (IDE) regulation, 21 CFR 812. Generally, FDA believes bone anchors addressed by this guidance document are significant risk devices subject to all requirements of 21 CFR 812. Please see the FDA guidance titled, "Significant Risk and Nonsignificant Risk Medical Device Studies" (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf). In addition to the requirements of 21 CFR 812, sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR 56) and informed consent (21 CFR 50).

K. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Proposed labels, labeling, and advertisements sufficient to describe the bone anchor, its intended use, and the directions for use must be provided with a specific intended use statement and any warnings, contraindications, or limitations clearly displayed as described in 21 CFR 807.87(e). You should use the following suggestions for assistance in preparing labeling that satisfies the requirements of 21 CFR 807.87(e).

As a prescription device, under 21 CFR 801.109, bone anchors are exempt from having adequate directions for lay use. Labeling must, however, include adequate information for practitioner use of the device, including indications, effects, routes, methods, frequency and duration of administration, and any relevant hazards, contraindications, side effects and precautions. (21 CFR 801.109(d)).

The labeling should include the following information:

Indications for Use

These devices are intended for reattachment of soft tissue (e.g., ligament and tendon) to bone at various anatomic locations. Different designs of anchor are suited for use at varying anatomic locations; therefore, we recommend that the indications for use are sufficiently detailed to specify the anatomic locations for the anchor components.

Directions for Use

The directions for use should familiarize users trained in orthopedic surgery with the features of the device and how to use it in a safe and effective manner, including assembly and insertion of anchor components for all of the proposed indications.

L. Modifications

In accordance with 21 CFR 807.81(a)(3), a device modification "that could significantly affect the safety or effectiveness of the device" or represents "a major change or modification in the intended use of the device" requires a new 510(k). FDA has determined that any one of the modifications listed below would generally require a new 510(k). Please note that this list is not exhaustive, but provides examples of modifications that will generally require a new 510(k).

A change or modification in the device that could significantly affect the safety or effectiveness of the device and would generally require a new 510(k) include:

- The addition of a smaller or larger anchor diameter than what was previously cleared or the addition of a smaller suture size – FDA considers these changes to be a significant change in design. FDA has determined that these changes could significantly affect the safety and effectiveness of the device by introducing a new potential worst-case scenario for some failure modes.

- A modification to the insertion technique (e.g., change from pre-drilled to self- punching) – FDA considers this change to be a significant change in design of the anchor or the instrumentation. FDA has determined that this change could significantly affect the safety and effectiveness of the device by altering the risk of adequate fixation.

- The modification of the material formulation of a bone anchor or a change to a new material such as from a non-absorbable to absorbable suture – FDA considers these changes to be a significant modification in material, chemical composition, or material processing. FDA has determined that these changes could significantly affect the safety and effectiveness of the device by introducing new or increased biocompatibility concerns or a change in the risks associated with device failure.

FDA believes that the following modifications will generally not require a new 510(k):

- Addition of a suture anchor of identical design and material to a cleared anchor, but of an intermediate length (e.g., 15mm length anchor added to a system with 10mm and 20mm lengths), or an increase in the length of a suture anchor inserter handle because neither scenario would generally introduce new or significantly modified risks or new worst-case failure modes.