Guidance for Industry and FDA Staff

Spinal System 510(k)s

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This document supersedes "Guidance for Spinal System 510(k)s" dated September 27, 2000.

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Center for Devices and Radiological Health

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

Orthopedic Devices Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Contains Nonbinding Recommendations

Table of Contents

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Guidance for Industry and FDA Staff

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Introduction

The purpose of this guidance document is to provide updated information regarding premarket notification (510(k)s) for spinal systems. This guidance document supersedes "**Guidance for Spinal System 510(k)s**" dated September 27, 2000.

The three primary differences between this version and the September 27, 2000 version are listed below.

1. System types have been redefined based on current indications for use.
2. The MNI product code, previously covering class II, class III preamendments, and unclassified pedicle screw uses, has been changed as follows:
    - the MNI product code now includes class II pedicle screw uses only
    - the NKB product code was developed for the class III preamendments pedicle screw uses of (1) degenerative disc disease, and (2) spondylolisthesis (other than severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurological impairment, which are both classified into class II as codified by 21 CFR 888.3070)
    - the NKG product code was developed for unclassified cervical pedicle screw uses.
3. Testing recommendations and indications for use for pedicle screw systems have been updated.

This guidance document was developed in response to discussions and correspondence between FDA and manufacturers of spinal systems, as well as in response to the publication of a final rule (63 FR 40025) classifying and reclassifying pedicle screw systems which became effective on August 26, 1998, as corrected by a Technical Amendment (66 FR 28501), which became effective on May 22, 2001. This guidance document also contains mechanical testing and material characterization input from the Orthopedic and Rehabilitation Devices Panel (the Panel) from the November 21, 2002 meeting.

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 document, "**A Suggested Approach to Resolving Least Burdensome Issues**". It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

Scope

A spinal system 510(k) typically involves one of the following:

- a new spinal system
- components to be added to a cleared spinal system
- expansion of indications for use of a cleared spinal system.

This guidance document is applicable to most plate and rod-based spinal systems indicated for fusion, as well as vertebral body replacement devices.

Each rod and plate-based spinal system may be described by one or more system types (e.g., a thoracolumbar anterior plate system and pedicle screw system). The different system types are described in more detail in **2. Device Description**.

This guidance document does not address facet screw fixation systems.

Although FDA recognizes that facet screw fixation systems were discussed in the 2000 version of this guidance document, these systems were removed from this updated version based on the limited number of submissions received each year. While you may use this guidance as a general framework for those systems, the Orthopedic Devices Branch is available to advise you further regarding your facet screw fixation system.

This guidance document also does not address interbody fusion and non-fusion devices (*i.e.*, cages or disc replacement devices) or other nonfusion spinal devices.

These devices are Class III devices and require the submission of premarket approval applications (PMAs) before they may be marketed. Studies of these devices must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812. FDA believes that these

devices are significant risk devices as defined in 21 CFR 812.3(m).[1] 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).

This guidance document contains information specific to spinal system 510(k)s. This document supplements other FDA documents regarding the content requirements of a 510(k) submission. You should also refer to CDRH's Device Advice http://www.fda.gov/cdrh/devadvice/ and 21 CFR 807.87. For general orthopedic 510(k) guidance, we recommend that you refer to the "**Guidance Document for the Preparation of Premarket Notification [510(K)] Applications For Orthopedic Devices**" that is available at http://www.fda.gov/cdrh/ode/832.pdf.

Specific Content for Spinal System 510(k)s

As stated above, this guidance document supplements other FDA documents regarding the information to be included in a 510(k) submission in accordance with 21 CFR 807.87. In addition to the general information, we recommend that you provide the following specific information for each spinal system 510(k) in the following order and format for ease of review.

1. Purpose of Your 510(k)

We recommend that you clearly state the purpose of your 510(k). For example, you should state whether your 510(k) seeks clearance for a new spinal system, adds a new component to a cleared spinal system, or proposes other modifications.

If your 510(k) is for a new spinal system, we recommend that you provide the name of the spinal system you intend to use for labeling purposes. If the 510(k) involves an expansion of components or indications for use of a cleared spinal system, we recommend that you identify the name of the spinal system being expanded and provide the number of the most recent 510(k) cleared for that spinal system.

2. Device Description

Defining System Type

Multiple regulations and product codes may be used to define a given system. FDA, however, has re-evaluated the manner in which we define a system type. FDA has traditionally focused on product code to define a system type. We believe that it will be easier to define a system type by its indication for use (e.g., anterior cervical fixation).

As stated in the **Introduction** section above, FDA developed new product codes for the different types of pedicle screw fixation, primarily to distinguish the different classes of pedicle screw use (i.e., class II, class III preamendments, and unclassified). Pedicle screw fixation systems are

[1] Refer to Blue Book Memorandum entitled "**Significant Risk And Nonsignificant Risk Medical Device Studies**" at http://www.fda.gov/cdrh/d861.html.

covered by product codes MNH, MNI, NKB, and NKG. The majority of the pedicle screw systems reviewed by FDA are covered by what would be currently defined as product codes MNH, MNI, and NKB.

In the past, the list of indications for use for a spinal system has because it included statements for each product code that a system fit. FDA has reviewed the available data for pedicle screws for the indication of degenerative disc disease and other spondylolistheses (spondylolisthesis uses not covered by MNI and MNH). After careful consideration, we believe that degenerative disc disease and other spondylolistheses can be included as part of the standard list of indications allowed for posterior, noncervical pedicle screw systems and that these indications fall within the intended use. Moreover, we believe these indications are well-supported and generally will not recommend clinical studies in new 510(k) submissions unless the design, technology, or indications are sufficiently dissimilar from legally marketed systems. By combining the pedicle screw indications covered by systems with product codes of MNH, MNI, and NKB, we now have one set of indications for a posterior, noncervical, pedicle screw spinal system. Systems with the product code of MNH were previously limited to specific types of spondylolisthesis in the lumbar spine but will now include all types of spondylolisthesis at all noncervical levels under the general indication of spondylolisthesis.

Moreover, the set of indications for a noncervical, pedicle screw system now parallels the indications for use of anterior and posterior, nonpedicle cervical systems. This greatly simplifies the statement of uses necessary for a given system.

Table 1a and **Table 1b** below summarizes for each spinal system that is subject to this guidance document, the product code the indications for use, class, and classification identification associated with that system. **Table 1a** details cervical systems and **Table 1b** details non-cervical systems.

Table 1a. Summary of Cervical System Types, Product Codes, and Indications for Use

System Type (Indication for Use)	Product Code	Indications for Use	Class	Classification Identification[A]
Anterior Cervical System	KWQ	• degenerative disc disease[B] • spondylolisthesis • trauma (*i.e.*, fracture or dislocation) • spinal stenosis • deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis) • tumor • pseudoarthrosis • failed previous fusion	II	888.3060
Posterior, Cervical, Nonpedicle System (*e.g.*, occipital system)	KWP	same as KWQ above	II	888.3050
Cervical, Pedicle System	NKG	• cervical spondylolisthesis (all grades and types) • cervical spondylolysis • cervical degenerative disc disease[B] • degeneration of the cervical facets accompanied by instability • cervical trauma (fracture and dislocation) • revision of failed previous fusion surgery (pseudoarthrosis) of the cervical spine	Unclassified[C]	

[A] Sections cited refer to Title 21 of the Code of Federal Regulations (CFR).

[B] You should include the definition for degenerative disc disease (DDD) as part of any statement of uses. DDD for cervical systems is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

[C] The regulatory pathway, i.e., premarket notification submission (510(k)), *de novo* classification, or premarket approval application (PMA), for device depends on the identification of an appropriate predicate device, the technology of the device, and its indications for use. See also "**New Section 513(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff**" at http://www.fda.gov/cdrh/modact/classiii.html. and "Premarket Approval" at http://www.fda.gov/cdrh/devadvice/pma/

Table 1b. Summary of Non-Cervical System Types, Product Codes, and Indications for Use

System Type	Product Code(s)	Indications for Use	Class	Classification Identification[A]
Anterior/ Anterolateral, Noncervical System	KWQ	• degenerative disc disease[B] • spondylolisthesis • trauma (*i.e.*, fracture or dislocation) • spinal stenosis • deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis) • tumor • pseudoarthrosis • failed previous fusion	II	888.3060
Posterior, Noncervical, Nonpedicle System	KWP	same as KWQ above	II	888.3050
Noncervical, Pedicle System	MNH MNI NKB[C]	same as KWQ above	II II III	888.3070(b)(1) 888.3070(b)(1) 888.3070(b)(2)
Vertebral Body Replacement Device/System	MQP	• tumor • trauma/fracture	II	888.3060

[A] Sections cited refer to Title 21 of the CFR.

[B] You should include the definition for degenerative disc disease (DDD) as part of any statement of uses. DDD for noncervical systems is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

[C] Systems intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment are class III. 21 CFR 888.3070(b)(2) You must provide a Class III Summary and Certification with your 510(k) in accordance with 21 CFR 807.87(j)(2) and 21 CFR 807.94.

Once you have determined the system type(s) and corresponding product code(s), indication(s) for use, class(es), and regulation number(s) appropriate for your system, we recommend that you clearly state this information at the beginning of your submission.

Specific Device Description Information

Depending on the system type involved, a given spinal system may consist of rods or plates, anterior screws, pedicle screws, sacral/iliac screws, hooks, connectors, crosslinks, fasteners, etc.

We recommend that you provide the following device description information:

- a table of components (see below for what should be included in this table)

- complete, dimensioned engineering drawings of each subject component
- a written description of the individual components and how the subject components interconnect (e.g., diameter of rods, sizes of screws, size/thickness of anterior plates, geometry of vertebral body replacement, type of screw/rod interconnection). Supporting sketches and/or photographs of the interconnection mechanisms may be useful
- a comparison of the largest profile of the device compared to a predicate device (if the device is implanted anteriorly or anterolaterally)
- identification of the materials from which the subject components are manufactured and any voluntary material standards to which these materials conform
- a magnified photograph and/or sketch of the spinal system attached to a spinal model
- information on the surgical instruments considered unique to the implantation of the subject system (i.e., list of surgical instruments, photograph(s)/drawing(s) of each, identification of materials from which they are manufactured, and any voluntary material standards to which these materials conform).

Table of Components

We recommend that you provide a table of components with your 510(k), whether it involves a new system or an addition of components or indications to a cleared system. The table should be. For a 510(k) involving an expansion of an already cleared spinal system (whether an expansion of components or indications for use), we recommend that you provide an all-inclusive list of components previously cleared and those under review for the given spinal system highlighting the components that have been added.

We recommend that you stratify the table into sections that are appropriate for the given system (*e.g.*, by material, vertical rod diameter, anterior versus posterior components). **Table 2** is an example of a component table.

Table 2. Sample Table of Components

Component Name	Part Number	Sizes (lengths and diameters)	Levels of Attachment	510(k) number[A]
Offset sacral screw	xx.xxx	XXmm-XXmm	L1-L5	KXXXXXX

[A] 510(k) in which component was cleared as part of the subject system or identification of the component as new

Please see **Frequently Asked Questions** at the end of this document for questions related to specific materials and other material questions.

3. Indications for Use

We recommend that you explicitly state the indication(s) for use for each spinal system at the beginning of your submission. We suggest that you avoid general and/or open-ended indications

(e.g., instability, disc herniation, or general spinal curvature). A single spinal system may have several sets of indications for use. However, based on FDA's re-evaluation of the system types and indications, the indication for use that appears in the labeling should be significantly clearer and more concise.

Below are examples of indication for use statements:

Example for anterior cervical system (product code KWQ):

The X System is intended for anterior cervical fixation for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Example for posterior thoracolumbar system (product codes KWP, MNI, MNH, NKB):

The X System is intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease(DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Example for anterior/anterolateral and posterior thoracolumbar system (product codes KWQ, KWP, MNI, MNH, NKB):

The X System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

4. Mechanical Testing

General Information

We recommend that you include mechanical testing or provide a rationale why mechanical testing is not necessary to support the substantial equivalence of your new component or system. Some rationales for not performing mechanical testing may involve the expansion of your spinal system to include additional components with the same interconnection mechanism, the use of components already part of that system, or the addition of components that do not cause the system to be susceptible to loosening or failure.

We recommend that you perform all testing on spinal assembly system constructs comprised of components in worst case (e.g., most likely to loosen or fail) final design version. You should also provide a rationale identifying how you identified the worst case spinal assembly. The components tested should comprise of the worst case constructs in terms of design, interconnection mechanism, materials, manufacturing-related processing, etc. We also recommend that you conduct testing on components with mechanical properties that could be affected by sterilization only after sterilization. Testing should involve the worst case construct of the total system, unless you have provided an adequate rationale for testing only individual components.

The Orthopedics Devices Branch is available to answer your questions about proposed testing set-ups to address a specific spinal system, identification of worst case constructs, or additional testing for a particular device.

Specific Testing Information

Table 3a and **Table 3b** below identify the type of mechanical testing that we recommend that you provide for each system type. However, depending on the specific design (e.g., anterior cord design), material (e.g., polymer, composite), and/or method of attachment, we may recommend additional testing (e.g., dynamic torsion testing, creep testing, subsidence testing) for a system. Refer to ***Fatigue and Static Testing Descriptions*** below for additional details regarding these types of tests. Refer to ***Test Report*** below for a description of the information you should include in a test report.

Table 3a. Testing Recommended for Cervical Spinal Systems

System Type	Product Code	Recommended Testing	Recommended Additional Information
Anterior, Cervical System	KWQ	• Static and dynamic axial compression bending testing • Static torsion testing	• A statement clarifying whether the system is intended for unilateral and/or bilateral fixation • A comparison of the worst case construct's width and prominence to a predicate system
Posterior Cervical, Nonpedicle System[A]	KWP	• Static and dynamic axial compression bending testing • Static and dynamic torsion testing	N/A
Cervical, Pedicle System	NKG	See KWP above	Clinical Studies

[A] If the system attaches to the occiput, we recommend that you provide dynamic torsion testing. In addition, a modified version of ASTM F1717 is recommended for testing constructs that are intended to be connected to the occiput. The Orthopedics Devices Branch is available to answer your questions about how we recommend that your system be tested.

Table 3b. Testing Recommended for Non-Cervical Spinal Systems

System Type	Product Code	Recommended Testing	Recommended Additional Information
Anterior, Noncervical System	KWQ	• Static and dynamic axial compression bending testing • Static torsion testing	• A statement clarifying whether the system is intended for unilateral and/or bilateral fixation • A comparison of the worst case construct's width and prominence to a predicate system
Posterior Noncervical, Nonpedicle System	KWP	• Static and dynamic axial compression bending testing • Static torsion testing	N/A
Noncervical, Pedicle System	MNI MNH NKB	• Static and dynamic axial compression bending testing • Static torsion testing	N/A
Vertebral Body Replacement Device/System (VBR)	MQP	• Static and dynamic axial compression bending testing • Static and dynamic torsion testing • Expulsion[A] For the dynamic axial compression bending tests, we recommend that you meet one of the following conditions: • asymptotic load level ≥ 3000N (~2x the vertebral body compression strength) at 5×10^6 cycles • asymptotic load level ≥ 1500N (~1x the vertebral body compression strength) at 10×10^6 cycles	• Depending on the design of the VBR system, we may recommend additional testing (*e.g.*, shear loading of a composite material, off-axis compression loading) • A clinical rationale for all sizes of the proposed VBR

[A] Expulsion testing may not be necessary for a VBR system that incorporates a supplemental fixation system that is physically attached to it (e.g., by a threaded bolt).

Static and Fatigue Testing Descriptions

Static construct testing should involve six or more samples of the worst case construct. We recommend that you provide the rationale for the components tested, loading mode, and testing configuration and environment (if applicable).

Fatigue construct testing is most commonly performed in accordance with American Society for Testing and Materials (ASTM) F1717 – 01 *"Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Vertebrectomy Model."* Except as noted below, we recommend that you use ASTM F1717 to provide a standard comparison to predicate device testing and to allow a declaration of conformity to that standard. However, you may choose alternative test methods that you show are substantially equivalent to the ASTM standard to address the mechanical loading issues at hand. ASTM F1717 is based on metallic spinal systems and may not be applicable to systems made out of other materials. Therefore, we may recommend additional testing and/or modifications to ASTM F1717 if the new system is manufactured out of a polymer or other materials.

The fatigue construct testing should involve six or more samples of the worst case construct to generate an Applied Force vs. Number of Cycles (AF/N) curve that characterizes the asymptotic endurance limit at a runout value of five million cycles compared to an appropriate predicate system. FDA recognizes that ASTM F1717 recommends a Stress versus Log number of cycles (S/N) curve; however, we believe that an AF/N curve provides similar information. We recommend that you test two or more samples at the lowest load level in order to establish a resulting endurance load limit.

Test Report

We recommend that you provide a complete test report that includes the following information:

- identification of the components that comprised the constructs or subconstructs tested
- the rationale for why those components comprised the worst case constructs or subconstructs
- the rationale for the loading modes chosen (e.g., axial, bending, torsion)
- identification of testing configuration and environment and a rationale for why that configuration and environment were chosen
- the results
- a discussion of the results in terms of the expected *in vivo* and clinical performance of the assembly
- if there are differences between the subject system and the system actually tested (*e.g.*, tests performed on prototype), an explanation of how or why the results are relevant in supporting a substantial equivalence determination.

Please see **Frequently Asked Questions** at the end of this document for additional testing

information.

5. Wear Testing

We recommend that you provide wear testing for a spinal system that raises issues of particulate generation (e.g., manufactured from novel materials (e.g., polymers, composites) or those containing articulating device components). We recommend that all wear testing be compared to a legally marketed predicate device with the same technological features and indications for use. You may be able to generate and evaluate wear debris as part of the fatigue testing or as part of a functional animal model. We recommend that the system be weighed before and after testing to evaluate mass loss during testing. We also recommend that you characterize all wear particulates (e.g., particle size and shape distribution, number of particles, and chemistry of particles) and analyze the articulating surfaces for scratches, burnishing, deformation, or any corrosion.

6. Animal Studies

For most spinal systems, animal studies are generally not necessary to assess the performance of these devices. However, the following are examples of certain circumstances under which FDA may recommend that you provide a complete report of animal testing:

- if the device has new or different indications
- if the device has novel design features
- if the device produces wear debris in differing amounts, size, or geometry during wear testing than the predicate device
- if the material has not been evaluated in the spine and/or the effects of the material on the spinal area and surrounding tissues and organs have not been evaluated
- if mechanical testing results do not compare favorably to the predicate device
- if mechanical testing alone cannot adequately characterize the device.

Animal studies are typically conducted to evaluate a biological response to a new material in the spine or to evaluate the functional behavior of a device system. If a system is manufactured from a material not currently used in the spine, or if it contains a component manufactured from a material that raises concerns of local and systemic adverse effects, we recommend that you conduct animal studies evaluating the biological effects of the material. FDA also recommends that you use a functional animal model to evaluate the actual use of the device system in situations where questions of device performance cannot be adequately answered by mechanical testing alone.

For functional animal studies, we recommend that you perform all testing on device components that are in final design and sterilized. However, for animal studies evaluating only the biological response of a new material with no device design and function issues, testing on the final, sterilized material may be adequate. For both types of animal studies, FDA recommends that a control group of animals be evaluated at the same timepoints as the investigational animals.

We recommend that you include the following information:

- identification of the animal model
- the rationale for why the animal model was chosen (e.g., relevance to human anatomy or disease)
- identification of the device components (i.e., what components were tested) or particles (i.e., size, quantity, and quality of particulates) used in the test
- the rationale for why those device components/particles were selected
- the evaluation timepoints of the study
- the number of animals (control and investigational) evaluated at each timepoint
- identification of the test control
- the results
- a discussion of the results in terms of the expected *in vivo* and clinical behavior of the device.

For a functional animal study, we recommend that all testing involve the worst case construct of the total system, rather than testing of individual components, unless an adequate rationale is provided. When there are differences between the subject system and the system actually tested (e.g., tests performed on prototype), you should provide an explanation of how or why the results are relevant to assessing the device.

7. Clinical Studies

In accordance with the Least Burdensome provisions of the Act, FDA will rely upon well-designed bench and/or animal testing rather than requiring clinical studies for a spinal system, unless there is a specific rationale for asking for clinical information to support a determination of substantial equivalence. For most spinal systems, a clinical study is generally not necessary to support a substantial equivalence determination. However, we may recommend that you conduct a supporting clinical study if your device has new uses, novel design features, or mechanical testing results that do not compare favorably to the predicate device.

For spinal systems with the product code NKG, we recommend a clinical study to support a substantial equivalence determination. Studies of these devices must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812. FDA believes that these devices are significant risk devices as defined in 21 CFR 812.3(m). 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). For information regarding clinical studies for spinal systems, we recommend that you refer to the "**Guidance Document for the Preparation of IDEs for Spinal Systems**" that is available at http://www.fda/gov/cdrh/ode/87.pdf. The Orthopedics Devices Branch is available to discuss your IDE protocol or your plans to conduct clinical studies outside the US.

8. Sterility

We recommend that you provide sterilization information for the finished spinal component or system in accordance with the "**Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**" that is available at http://www.fda.gov/cdrh/ode/guidance/361.html.

9. Modifications to Legally Marketed Devices: Special 510(k)s

Under **"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 a Special 510(k) for certain modifications of legally marketed devices. A manufacturer considering modifications to its own cleared device may lessen the regulatory burden by submitting a Special 510(k).

10. 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 Part 801.[2]

Package Label

We recommend that you include the following items on your package label:

- component name
- statement referring to package insert for labeling limitations (e.g., "see package insert for labeling limitations")
- part number/lot number (if applicable)
- shelf life (if applicable)
- material
- sterile or non-sterile notation.

Package Insert

We recommend that you include the following information in your package insert:

- system name

[2] 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.

- specific indications for use, including levels of fixation
- precaution statement addressing the relationship between fatigue testing and device performance, for example: "Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system."
- sterile or nonsterile notation
- recommended sterilization process parameters if the device is provided nonsterile or if resterilization is allowed.

We also recommend that you include a brief device description with identification of material(s). This description should clearly identify any trade name components from other spinal systems that are used with the subject system. For vertebral body replacement systems, the device description should also identify each specific supplemental fixation system indicated for use with and/or attached to the subject system.

If your system is intended only for uses identified with KWQ or KWP product codes, we recommend that you include a warning addressing some of its limitations, for example:

> ***Warning:*** This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

However, if your system has pedicle screw uses (MNI, MNH, NKB product codes) with or without KWP or KWQ product code uses, the following warning and precaution must be included in your package insert (21 CFR 888.3070):

> *"**Warning:** The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown."*
>
> *and*
>
> *"**Precaution:** The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient."*

Depending on the performance of your device, FDA may recommend that you include additional information, warnings, or precautions in the package insert.

Surgical Technique Manual

We recommend that you provide a draft surgical technique manual if the system has unique design features, such as a vertebral body replacement (MQP product code). Generally, we recommend that the surgical technique manual include the following information:

- a list of the intended uses and indications, device description, contraindications, precautions, and warnings associated with the subject system
- interconnection and spinal attachment instructions
- supporting magnified sketches of the major steps
- identification of each supplemental fixation system used with or attached to the subject system (specific to vertebral body replacement systems)
- removal or revision procedures.

Frequently Asked Questions

The following frequently asked questions are provided to further assist you in developing a spinal system 510(k).

1. How do I determine what is my worst case construct?

The most appropriate worst case spinal assembly construct typically depends on the device design and the test. The test being done may determine which component should be the weakest or most failure-prone part of the construct. We recommend that you explain how each component was chosen for each worst case construct. In addition, you may test the different interconnection mechanisms in the same construct or each in a separate construct. However, we recommend that you test each interconnection mechanism or provide an adequate rationale for those not tested.

Typical examples of worst case constructs are listed below.

Pedicle screw, rod, and hook type systems

We recommend that you evaluate the smallest diameter rod and smallest diameter screws as worst case for static and fatigue testing. Cross-connectors should be used in both static and dynamic compression bending tests, but should not be used in static torsion tests. In addition, for static and dynamic testing, we recommend you provide a rationale for testing or not testing the transverse connector.

Vertebral body replacements

We recommend that the tallest components with the smallest cross sectional area be evaluated without supplemental fixation for all compression bending tests and torsion tests. We recommend that you evaluate the components with the smallest cross sectional area in all compression tests.

2. What should I provide if my vertebral body replacement does not perform as

recommended by this guidance?

If your VBR does not perform as recommended in **Table 3b**, you should test the worst case vertebral body replacement in conjunction with the worst case supplemental fixation system for which it is intended to be used. You should identify that as the only system indicated for use in conjunction with the VBR. In addition, we recommend that you provide the 510(k) number for each system tested with the VBR.

3. What type of information should I provide if my spinal system contains polyethylene or some other polymer?

If the system or any component of the system is manufactured from Ultra High Molecular Weight Polyethylene, we recommend that you provide the information detailed in the guidance entitled, "**Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices**" that is available at http://www.fda.gov/cdrh/ode/180.pdf.

If the system or any component of the system is manufactured from any other polymer (e.g., Polyetheretherketone), we recommend that you provide a characterization of the material (e.g., biocompatibility information and/or leachables, material properties, molecular weight, molecular weight distribution, chemical and crystal structures, percent of crystallinity, the degree of cross-linking of that polymer) for the raw material, as well as the final sterilized material. In addition, we recommend that you provide a brief summary of the material processing and any solvents used throughout the manufacturing of the components or spinal system.

For any materials that are manufactured from polymers or that have the potential for leachables, you should perform an exhausted extraction analysis of the final sterilized device. Extractions should be done using both a polar (e.g., saline) and a non-polar solvent (e.g., hexane, acetonitrile). Some solvents may be appropriate for certain materials; you should provide a rationale for the solvents chosen for the extraction tests. The test report should include, but need not be limited to, the instrument sensitivities, type of solvent used, the amount of leachables and impurities detected at part-per-billion (ppb) levels, etc. We recommend that you identify each leachable and impurity that is detected qualitatively and quantitatively, including any low molecular weight materials, residual monomers, solvent, sulfur contents, catalysts, initiators, lubricants, etc.

We may also recommend general biocompatibility testing based on the material(s) used to comprise the system. International Standards Organization (ISO) 10993 is a recognized standard that can be referenced for a description of the type of information that should be provided to address biocompatibility. Please refer to the guidance entitled, "**Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing**" at the following web site for additional information: http://www.fda.gov/cdrh/g951.html.

In addition, we may recommend animal testing involving the response to the material in the spine (see **6. Animal Studies**).

If the system or any component of the system is manufactured from a material that may be affected by aging, we recommend you provide a material characterization and possible mechanical testing evaluating

the aging effects. We recommend that you perform chemical analyses to characterize the material per the parameters outlined above.

If the identical material is used in a predicate device with the same indications and spinal levels, you may identify the predicate device in lieu of providing the above information. You should submit a direct material comparison between the predicate device and your device showing that both devices are manufactured from identical materials.

4. Can I submit one 510(k) that affects more than one spinal system?

FDA generally recommends that you submit separate 510(k)s for each spinal system because of the number and diversity of components contained in each system or when these systems have different indications or are supported by information. Another example where separate 510(k)s are appropriate is for the addition of a component to several different spinal systems. Here again the diversity of indications and supporting information will likely make a bundled 510(k) unnecessarily burdensome. However, bundling of class I or II spinal implant made of different metallic alloys (e.g., a stainless steel and titanium version) into one 510(k) may be appropriate, if the indications for use are generally the same for the two materials. For additional information about bundling, see the guidance entitled "**Bundling Multiple Devices or Multiple Indications in a Single Submission**" http://www.fda.gov/cdrh/mdufma/guidance/1215.html.

5. What should I do if my spinal system contains components from another one of my previously cleared spinal systems?

If your system (System X) includes components cleared in another one of your own systems (System Y), we recommend that you clearly state in the subject 510(k) whether the System Y components will keep their original cleared trade name or whether they will be relabeled to reflect the System X trade name. Additionally, we recommend that you include the components for System Y in the table of components for System X.

If you choose to keep the original cleared System Y trade name, then the table listing should reflect that trade name. You should provide the device description information described above for these components, specific to the use with the new system (System X).

6. What should I do if my device can be affected by aging or shelf life?

We recommend you evaluate all spinal systems or spinal components (e.g., polymers) that can be affected by shelf life or aging. You should characterize the material before and after aging to see if aging altered the material structure (e.g., molecular weight distribution, crystallinity, cross-linking). The material in this study should be the material used in the final design and should be sterilized using the same method as intended for the marketed device. See **2. Device Description** for material properties. You should choose a validated method of aging. If shelf life or aging affects the component's material, you should perform mechanical testing of that component or system using the same mechanical tests performed before the device was aged.

If FDA has cleared a 510(k) that contains aging testing on the identical material for the same indications

and same spinal levels, you may reference that 510(k) and those material evaluations instead of providing the characterization studies described. In this case, we recommend that you provide a direct comparison of the identity, composition, and grade of the materials used in the cleared device and your device, showing that they are comprised of the identical materials for the same indications.

7. What if my 510(k) only involves the addition of new components, such as smaller screws?

Although we generally recommend construct testing, if you are adding a new component to an already existing spinal system (e.g., a component with a different interconnection mechanism) that could create a potentially weaker system, we recommend that you test an assembly of those components and compare the results to an already cleared assembly of similar components. We recommend ASTM F1798 – 97 "*Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants*" for assembly test methodology. For the addition of a new component, where it is clear that a potentially weaker system will not be created, we continue to recommend construct testing.