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Spinal Plating Systems – Performance Criteria for Safety and Performance Based Pathway

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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For questions about this document, contact the DHT6B: Division of Spinal Devices at 301-796-5650 or Jonathan Peck at Jonathan.Peck@fda.hhs.gov.

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

Preface

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Spinal Plating Systems – Performance Criteria for Safety and Performance Based Pathway

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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This draft guidance provides performance criteria for spinal plating systems in support of the Safety and Performance Based Pathway.[1] Under this framework, submitters planning to submit a 510(k) using the Safety and Performance Based Pathway for spinal plating systems will have the option to use the performance criteria proposed in this draft guidance to support substantial equivalence, rather than a direct comparison of the performance of the subject device to that of a predicate device.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[2] For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.[3]

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities.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

[1] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway

[2] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Scope/Device Description

The spinal plates that are the subject of this guidance are anterior cervical or anterior/lateral thoracolumbar spinal plating systems. These devices are Class II and are regulated under 21 CFR 888.3060 with the product code KWQ (appliance, fixation, spinal intervertebral body). General guidance on submission of a 510(k) for a spinal plating system can be found in FDA's guidance Spinal System 510(k)s.[4]

Intended Use/Indications for Use: The spinal plating systems that fall within the scope of this guidance document are intended for fixation to vertebral bodies (anteriorly in the cervical spine or anteriorly/laterally in the thoracolumbar spine) for the purpose of stabilizing the spine for fusion. Plating systems that attach to the posterior spine are outside the scope of this guidance document.

Device Design Characteristics: The spinal plating systems that fall within the scope of this guidance document consist of plates and associated fixed or variable angle screws, constructed solely from one of the following titanium alloys in conformance with the associated FDA-recognized consensus standard:

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

A dimensional comparison of the subject device should be performed, and the dimensions should fall within the dimensional ranges listed in Table 1.

[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-fda-staff-spinal-system-510ks

Table 1 - Size ranges for cervical and thoracolumbar spinal plating systems.

Cervical Plates	**Range***
Number of Levels Treated	1 to 5
Plate Length (hole-to-hole)	10 mm to 115 mm
Plate Thickness/Profile**	≤ 3 mm
Screw Diameter (Major)	3.5 mm to 4.5 mm
Screw Length (Threaded Length)	10 mm to 26 mm
Thoracolumbar Plates	
Number of Levels Treated	1 to 3
Plate Length (hole-to-hole)	15 mm to 130 mm
Plate Thickness/Profile**	≤ 7 mm
Screw Diameter (Major)	5 mm to 7 mm
Screw Length (Threaded Length)	15 mm to 70 mm

* The dimensional ranges listed were derived from historical data submitted to FDA in 510(k) submissions for devices previously found substantially equivalent.

** Largest thickness or profile of the subject plate should fall below the listed value.

Cervical and thoracolumbar spinal plating systems with the following features are not eligible for the Safety and Performance Based Pathway via this guidance:

- Devices that affix to the posterior spine
- Devices for which a 2-level cervical plate or a 1- or 2-level thoracolumbar plate is not representative of a worst-case construct for performance testing per the FDA currently recognized version of ASTM F1717 *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*
- Staples or plates with fixation mechanisms other than threaded screws
- Devices with coatings
- Combination products
- Resorbable devices
- Additively manufactured devices
- Devices that are designed to allow motion post-implantation (e.g., plates designed to "settle").
- Buttress plating systems (i.e., plates that do not span at least one functional spinal unit)

Where FDA determines that additional data are necessary to make these determinations, the Agency may, on a case-by-case basis, review that data before determining whether or not the device is appropriate for the Safety and Performance Based Pathway. In situations, where you determine that additional testing outside of those identified in this guidance are necessary to make a determination regarding eligibility into the Safety and Performance Based Pathway, we

would encourage sponsors to submit a Pre-Submission[5] to engage in discussion with FDA prior to submission of the 510(k).

III. Testing Performance Criteria

If your device is appropriate for submission through the Safety and Performance Based Pathway, and you choose to use that option, you do not need to provide direct comparison testing against a legally marketed predicate to demonstrate substantially equivalent performance characteristics. To ensure that the performance criteria outlined in this guidance remain contemporary and take into account relevant data from recent clearances, FDA recommends that you provide a results summary for all tests evaluated in addition to the other submission information (e.g., Declaration of Conformity (DoC)) identified for each test or evaluation below. Unless otherwise identified in the submission information sections below, test information such as results summary, test protocols, or complete test reports should be submitted as part of the 510(k) as described in FDA's guidance, Safety and Performance Based Pathway.[6] For additional information regarding the submission of non-clinical bench testing information, please see FDA's guidance Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions.[7]

Mechanical Testing

Static compression bending, static torsion, and dynamic compression bending should be performed in conformance with the FDA currently-recognized version of ASTM F1717 *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*. We recommend that you perform all testing on plate system designs that represent worst-case (e.g., most likely to loosen or fail) final design versions. You should also provide a rationale identifying how you identified the worst-case design. Acceptance criteria are listed below for each test, which include stiffness and yield values for the static tests and runout loads for the dynamic test.[8]

For each mechanical test below, you should provide a report as specified in the relevant reporting sections of ASTM F1717 and the Mechanical Testing section of FDA's guidance Spinal System 510(k)s,[9] in addition to a Declaration of Conformity (DoC) to the consensus standard. Any

[5] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

[6] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway

[7] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket

[8] It should be noted that although ASTM F1717 is FDA-recognized in full, FDA believes that for the purposes of the safety and performance based pathway, the testing, methods and criteria identified in this section on mechanical bench testing represent the least burdensome approach to demonstrating substantial equivalence for this pathway, although alternative or additional methods or acceptance criteria are identified in the recognized consensus standard for some tests.

[9] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-fda-staff-spinal-system-510ks

protocol deviations should be thoroughly described and justified; however, note that certain protocol deviations may invalidate comparison to the performance criteria listed below, resulting in the need for submission of a Traditional, Special, or Abbreviated 510(k), as appropriate.

Note: ASTM F1717 specifies the active lengths of the longitudinal element to be 35 mm for cervical devices and 76 mm for lumbar devices (or as close to these dimensions as possible based on plate sizes available) to simulate connection across two spinal levels in the cervical and lumbar spine, respectively. However, since many thoracolumbar plating systems only contain 1-level plates, significant modification to the specified 76 mm active length is necessary to simulate connection across a single spinal level. Therefore, data for 1-level and 2-level thoracolumbar plating systems were analyzed separately, and acceptance criteria are stratified for each test below.

1. **Test name:** ASTM F1717 - Static compression bending
   Methodology: ASTM F1717 *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*
   Performance Criteria:

   Table 2 –Static compression bending acceptance criteria for cervical and thoracolumbar plating systems

Test Parameter	Cervical (2-Level constructs)	Thoracolumbar (1-level constructs)	Thoracolumbar (2-level constructs)
Static Compression Bending Stiffness (N/mm)	9.6 N/mm	45 N/mm	35 N/mm
Static Compression Bending Yield (N)	75 N	230 N	360 N

   Performance Criteria Source: Criteria are based on aggregated mechanical testing data submitted to FDA in 510(k) submissions for spinal plating systems previously found to be substantially equivalent.
   Additional Considerations: Testing should include a minimum of 5 samples consistent with ASTM F1717. In order to be considered a successful result, either: (1) all samples should meet or exceed the acceptance criteria listed above, or (2) the average of all samples should meet or exceed the criteria above and the standard deviation should be ≤ 10% of the calculated average. For testing of 1-level thoracolumbar plates, active length for the worst case should fall between 25 and 40 mm to be comparable to the criteria listed in the table above.
   Submission Information: Results summary and DoC

2. **Test name:** ASTM F1717 - Static torsion
   Methodology: ASTM F1717 *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*

Performance Criteria:

Table 3 – ASTM F1717 static torsion acceptance criteria for cervical and thoracolumbar plating systems.

Test Parameter	Cervical (2-Level constructs)	Thoracolumbar (1-level constructs)	Thoracolumbar (2-level constructs)
Static Torsion Stiffness (N-m/degree)	0.9 N-m/degree	5.6 N-m/degree	2.7 N-m/degree
Static Torsion Yield (N-m)	4.7 N-m	19 N-m	18 N-m

Performance Criteria Source: Criteria are based on aggregated mechanical testing data submitted to FDA in 510(k) submissions for spinal plating systems previously found to be substantially equivalent.
Additional Considerations: Testing should include a minimum of 5 samples consistent with ASTM F1717. In order to be considered a successful result, either: (1) all samples should meet or exceed the acceptance criteria listed above, or (2) the average of all samples should meet or exceed the criteria above and the standard deviation should be ≤ 10% of the calculated average. For testing of 1-level thoracolumbar plates, active length for the worst case should fall between 25 and 40 mm to be comparable to the criteria listed in the table above.
Submission Information: Results summary and DoC

3. **Test name:** ASTM F1717 - Dynamic compression bending fatigue test
Methodology: ASTM F1717 *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*
Performance Criteria:

Table 4 – ASTM F1717 dynamic compression bending acceptance criteria for cervical and thoracolumbar plating systems.

Test Parameter	Cervical (2-Level constructs)	Thoracolumbar (1-level constructs)	Thoracolumbar (2-level constructs)
Dynamic Compression Bending Runout Load to 5 Mc (N)	40 N	165 N	165 N

Performance Criteria Source: Criteria are based on aggregated mechanical testing data submitted to FDA in 510(k) submissions for spinal plating systems previously found to be substantially equivalent.

Additional Considerations: Fatigue testing should include a minimum of 6 samples with at least two runouts at the highest established runout load and at least one failure. Fatigue precision (the ratio of the lowest failure load to the highest established runout) should meet the level specified in ASTM F1717. For testing of 1-level thoracolumbar plates, active length for the worst case should fall between 25 and 40 mm to be comparable to the criteria listed in the table above.
Submission Information: Results summary and DoC

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

4. **Test name:** Sterilization (devices labeled as sterile) and Reprocessing (end-user sterilized)
Methodology: FDA currently-recognized versions of the following consensus standards (as applicable):
    - International Organization for Standardization (ISO) 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*
    - ISO 11135-1 *Sterilization of health care products – Ethylene oxide- Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*
    - ISO 11137-1 *Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*
    - ISO 11607-1 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
    - ISO 11607-2 *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*

    Performance Criteria: Validation testing should demonstrate the cleanliness and sterility of, or the ability to clean and sterilize to a sterility assurance level of 10^{-6}, the device and device-specific instruments. You should provide a description of the packaging (sterile barrier system) and how it will maintain the device's sterility, and a description of the package test methods, but not package test data.
    Performance Criteria Source: FDA's guidance:
    - Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile[10]
    - Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling[11]

    Submission Information: If using an Established Category A sterilization method, you should provide the information described in Section V.A. as specified in the FDA guidance Submission and Review of Sterility Information in Premarket Notification

[10] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled
[11] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling

(510(k)) Submissions for Devices Labeled as Sterile; the validation data itself is not needed to demonstrate substantial equivalence.

Biocompatibility Evaluation:

To identify the biocompatibility endpoints to include as part of your biocompatibility evaluation you should use Attachment A of CDRH's guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,[12] referred to in the rest of this document as the "CDRH Biocompatibility Guidance" for brevity. FDA considers the devices covered by this guidance to be categorized as Implant Devices in contact with tissue/bone with a permanent contact duration of > 30 days and you should assess the endpoints below per Attachment A of the CDRH Biocompatibility Guidance.

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

Rationale in Lieu of Testing: If the subject device is manufactured from the identical raw materials using identical manufacturing processes as a predicate device with the same type and duration of tissue contact, and any changes in geometry are not expected to impact the biological response, this is typically sufficient to establish substantially equivalent biocompatibility if documentation such as that outlined in Attachment F of the CDRH Biocompatibility Guidance is also provided.

Testing: In rare cases, if you determined that testing is needed to address some or all of the identified biocompatibility endpoints, FDA recommends that complete test reports be provided for all tests performed unless a declaration of conformity without supplemental information can be appropriately provided, per Attachment E of the CDRH Biocompatibility Guidance. Any test-specific positive, negative, and/or reagent controls should perform as expected, and protocol deviations should be thoroughly described and justified; however, note that certain protocol deviations may invalidate comparison to the performance criteria listed below, resulting in the need for submission of a Traditional, Special, or Abbreviated 510(k).

[12] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and

5. **Test name:** Biocompatibility endpoints (identified from CDRH Biocompatibility Guidance)
Methodology: FDA currently-recognized versions of biocompatibility consensus standards
Performance Criteria: All direct or indirect tissue contacting components of the device and device-specific instruments should be determined to have an acceptable biological response.
Performance Criteria Source: The CDRH Biocompatibility Guidance
Additional Considerations: For any biocompatibility test samples with an adverse biological response, the biocompatibility evaluation should explain why the level of toxicity seen is acceptable. Some comparison testing against a legally marketed predicate may be necessary (and is considered acceptable under the Safety and Performance Based Pathway) to support such a rationale as explained in the CDRH Biocompatibility Guidance. For standard biocompatibility test methods that include comparison device control samples, the legally marketed comparison device control samples should perform as expected, as specified above for the subject device samples.
Submission Information: Refer to CDRH Biocompatibility Guidance