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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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on September 20, 2019.

16 You should submit comments and suggestions regarding this draft document within 90 days of 17 publication in the *Federal Register* of the notice announcing the availability of the draft

18 guidance. Submit electronic comments to https://www.regulations.gov. Submit written

19 comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630

20 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number

21 listed in the notice of availability that publishes in the *Federal Register*.22

For questions about this document, contact the DHT6B: Division of Spinal Devices at 301-7965650 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

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Preface

31 32

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- 34
- 35 Additional copies are available from the Internet. You may also send an e-mail request to
- 36 <u>CDRH-Guidance@fda.hhs.gov</u> to receive a copy of the guidance. Please include the document
- 37 number 19008 and complete title of the guidance in the request.
- 38

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51 52 This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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.

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54 I. Introduction

- 55 This draft guidance provides performance criteria for spinal plating systems in support of the
- 56 <u>Safety and Performance Based Pathway</u>.¹ Under this framework, submitters planning to submit a
- 57 510(k) using the Safety and Performance Based Pathway for spinal plating systems will have the
- 58 option to use the performance criteria proposed in this draft guidance to support substantial
- 59 equivalence, rather than a direct comparison of the performance of the subject device to that of a 60 predicate device.
- 61
- 62 For the current edition of the FDA-recognized standard(s) referenced in this document, see the
- 63 <u>FDA Recognized Consensus Standards Database</u>.² For more information regarding use of
- 64 consensus standards in regulatory submissions, please refer to the FDA guidance titled
- 65 Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical
- 66 <u>Devices.</u>³
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- 68 FDA's guidance documents, including this draft guidance, do not establish legally enforceable 69 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should

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

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

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

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70 be viewed only as recommendations, unless specific regulatory or statutory requirements are

71 cited. The use of the word *should* in Agency guidance means that something is suggested or

72 recommended, but not required.

73

74 II. Scope/Device Description

75 The spinal plates that are the subject of this guidance are anterior cervical or anterior/lateral 76 thoracolumbar spinal plating systems. These devices are Class II and are regulated under 21 CFR 77 888.3060 with the product code KWQ (appliance, fixation, spinal intervertebral body). General 78 guidance on submission of a 510(k) for a spinal plating system can be found in FDA's guidance 79 Spinal System 510(k)s.⁴

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81 **Intended Use/Indications for Use**: The spinal plating systems that fall within the scope of this 82 guidance document are intended for fixation to vertebral bodies (anteriorly in the cervical spine 83 or anteriorly/laterally in the thoracolumbar spine) for the purpose of stabilizing the spine for 84 fusion. Plating systems that attach to the posterior spine are <u>outside the scope</u> of this guidance 85 document.

86

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

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

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102 **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

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104 * The dimensional ranges listed were derived from historical data submitted to FDA in 510(k) submissions for

105 devices previously found substantially equivalent.

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

107

108 Cervical and thoracolumbar spinal plating systems with the following features are <u>not</u> eligible

109 for the Safety and Performance Based Pathway via this guidance:

- 110 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
- 116 Devices with coatings
- Combination products
- 118 Resorbable devices
- 119 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)
- 123
- 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

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would encourage sponsors to submit a Pre-Submission⁵ to engage in discussion with FDA prior 129

- 130 to submission of the 510(k).
- 131

III. Testing Performance Criteria 132

133 If your device is appropriate for submission through the Safety and Performance Based Pathway, 134 and you choose to use that option, you do not need to provide direct comparison testing against a 135 legally marketed predicate to demonstrate substantially equivalent performance characteristics. 136 To ensure that the performance criteria outlined in this guidance remain contemporary and take 137 into account relevant data from recent clearances, FDA recommends that you provide a results 138 summary for all tests evaluated in addition to the other submission information (e.g., Declaration 139 of Conformity (DoC)) identified for each test or evaluation below. Unless otherwise identified in 140 the submission information sections below, test information such as results summary, test 141 protocols, or complete test reports should be submitted as part of the 510(k) as described in 142 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 143 144 Recommended Content and Format of Non-Clinical Bench Performance Testing Information in

- 145 Premarket Submissions.⁷
- 146

147 **Mechanical Testing**

- 148
- 149 Static compression bending, static torsion, and dynamic compression bending should be
- performed in conformance with the FDA currently-recognized version of ASTM F1717 150
- 151 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model. We recommend
- 152 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 153
- 154 identified the worst-case design. Acceptance criteria are listed below for each test, which
- 155 include stiffness and yield values for the static tests and runout loads for the dynamic test.⁸
- 156
- For each mechanical test below, you should provide a report as specified in the relevant reporting 157
- 158 sections of ASTM F1717 and the Mechanical Testing section of FDA's guidance Spinal System
- 159 510(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-andmeetings-medical-device-submissions-q-submission-program

⁶ Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performancebased-pathway

⁷ Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-contentand-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 <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-</u> fda-staff-spinal-system-510ks

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160 protocol deviations should be thoroughly described and justified; however, note that certain

161 protocol deviations may invalidate comparison to the performance criteria listed below, resulting

162 in the need for submission of a Traditional, Special, or Abbreviated 510(k), as appropriate.

163

164 **Note:** ASTM F1717 specifies the active lengths of the longitudinal element to be 35 mm for

165 cervical devices and 76 mm for lumbar devices (or as close to these dimensions as possible based

166 on plate sizes available) to simulate connection across two spinal levels in the cervical and

167 lumbar spine, respectively. However, since many thoracolumbar plating systems only contain 1-

168 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

170 thoracolumbar plating systems were analyzed separately, and acceptance criteria are stratified for 171 each test below.

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173 1. Test name: ASTM F1717 - Static compression bending

174Methodology: ASTM F1717 Standard Test Methods for Spinal Implant Constructs in a175Vertebrectomy Model

176 **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

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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.

185Additional Considerations: Testing should include a minimum of 5 samples consistent186with ASTM F1717. In order to be considered a successful result, either: (1) all samples187should meet or exceed the acceptance criteria listed above, or (2) the average of all188samples should meet or exceed the criteria above and the standard deviation should be \leq 18910% of the calculated average. For testing of 1-level thoracolumbar plates, active length190for the worst case should fall between 25 and 40 mm to be comparable to the criteria191listed in the table above.

192 Submission Information: Results summary and DoC193

194 2. **Test name:** ASTM F1717 - Static torsion

195 Methodology: ASTM F1717 Standard Test Methods for Spinal Implant Constructs in a

196 Vertebrectomy Model

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199 200	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	
201					
.02					
203			based on aggregated n	6	
04			r spinal plating systems	previously found to	
05	be substantially equiva		1 in altrada a minimum a	65 annulas consisten	
06	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				
07	with ASTM F1717. In	order to be considered	d a successful result, et	ither: (1) all samples	
.07 .08	with ASTM F1717. In should meet or exceed	order to be considered the acceptance criter	d a successful result, et ia listed above, or (2) th	ither: (1) all samples ne average of all	
207 208 209	with ASTM F1717. In should meet or exceed samples should meet c	order to be considere the acceptance criter r exceed the criteria a	d a successful result, et ia listed above, or (2) the bove and the standard	ither: (1) all samples ne average of all deviation should be <u>s</u>	
207 208 209 210	with ASTM F1717. In should meet or exceed samples should meet of 10% of the calculated	order to be considered the acceptance criteria or exceed the criteria a average. For testing o	d a successful result, et ia listed above, or (2) th bove and the standard f 1-level thoracolumba	ither: (1) all samples ne average of all deviation should be <u><</u> r plates, active length	
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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.

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235 Sterilization (devices labeled as sterile) and Reprocessing (end-user sterilized) Validation 236 4. Test name: Sterilization (devices labeled as sterile) and Reprocessing (end-user sterilized) 238 sterilized) 239 Methodology: FDA currently-recognized versions of the following consensus standards (as applicable): 241 • 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 244 • 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 247 • 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 250 • ISO 11607-1 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems 251 Requirements for forming, sealing and assembly processes 254 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 package test methods, but not package test data. 255 Performance Criteria Source: F	227 228 229 230 231 232 233 234		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
 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 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 1107-1 Packaging for terminally sterilized medical devices – Part 1: Requirements for development, solitaging and assembly processes 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 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 I abeled as Sterile¹⁰ Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling¹¹ 		<u>Steril</u>	ization (devices labeled as sterile) and Reprocessing (end-user sterilized) Validation
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266 guidance <u>Submission and Review of Sterility Information in Premarket Notification</u>	266		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 <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-</u> <u>devices-health-care-settings-validation-methods-and-labeling</u>

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267 (510(k)) Submissions for Devices Labeled as Sterile; the validation data itself is not needed to demonstrate substantial equivalence. 268 269 270 **Biocompatibility Evaluation:** 271 272 To identify the biocompatibility endpoints to include as part of your biocompatibility evaluation 273 you should use Attachment A of CDRH's guidance Use of International Standard ISO 10993-1, 274 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 275 276 Guidance" for brevity. FDA considers the devices covered by this guidance to be categorized as 277 Implant Devices in contact with tissue/bone with a permanent contact duration of > 30 days and 278 you should assess the endpoints below per Attachment A of the CDRH Biocompatibility 279 Guidance. 280 • Cytotoxicity 281 • Sensitization 282 • Irritation or Intracutaneous Reactivity 283 • Acute Systemic Toxicity 284 • Material-Mediated Pyrogenicity 285 Sub-acute/Sub-chronic Toxicity • 286 Genotoxicity • 287 • Implantation 288 • Chronic Toxicity 289 • Carcinogenicity 290

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.

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298 Testing: In rare cases, if you determined that testing is needed to address some or all of the 299 identified biocompatibility endpoints, FDA recommends that complete test reports be provided 300 for all tests performed unless a declaration of conformity without supplemental information can 301 be appropriately provided, per Attachment E of the CDRH Biocompatibility Guidance. Any test-302 specific positive, negative, and/or reagent controls should perform as expected, and protocol 303 deviations should be thoroughly described and justified; however, note that certain protocol 304 deviations may invalidate comparison to the performance criteria listed below, resulting in the 305 need for submission of a Traditional, Special, or Abbreviated 510(k). 306

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

Draft – Not for Implementation

- 308 5. Test name: Biocompatibility endpoints (identified from CDRH Biocompatibility 309 Guidance) 310 Methodology: FDA currently-recognized versions of biocompatibility consensus 311 standards 312 Performance Criteria: All direct or indirect tissue contacting components of the device 313 and device-specific instruments should be determined to have an acceptable biological 314 response. Performance Criteria Source: The CDRH Biocompatibility Guidance 315 316 Additional Considerations: For any biocompatibility test samples with an adverse biological response, the biocompatibility evaluation should explain why the level of 317 318 toxicity seen is acceptable. Some comparison testing against a legally marketed predicate 319 may be necessary (and is considered acceptable under the Safety and Performance Based 320 Pathway) to support such a rationale as explained in the CDRH Biocompatibility 321 Guidance. For standard biocompatibility test methods that include comparison device 322 control samples, the legally marketed comparison device control samples should perform 323 as expected, as specified above for the subject device samples.
- 324 Submission Information: Refer to CDRH Biocompatibility Guidance