



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Stryker Spine  
Deborah Cynamon  
Regulatory Affairs Specialist  
2 Pearl Court  
Allendale, New Jersey 07401

September 6, 2017

Re: K171496  
Trade/Device Name: Tritanium® C Anterior Cervical Cage  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: ODP  
Dated: August 4, 2017  
Received: August 7, 2017

Dear Ms. Cynamon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

  
Katherine D. Kavlock -S

for  
Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K171496

Device Name

Tritanium® C Anterior Cervical Cage

Indications for Use (Describe)

The Tritanium® C Anterior Cervical Cage is indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels from the C2 to T1 disc.

DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have six weeks of non-operative therapy.

The Tritanium® C Anterior Cervical Cage System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach.

The Tritanium® C Anterior Cervical Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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<b>510(k) Summary as required by 21 CFR §807.92(c). Tritanium® C Anterior Cervical Cage</b>	
Submitted by	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Deborah Cynamon Regulatory Affairs Specialist Phone: 201 749 8388 Email: Deborah.cynamon@stryker.com
Date Prepared	September 6, 2017
Common Name	Intervertebral body fusion device
Trade Name	Tritanium® C Anterior Cervical Cage
Proposed Class	Class II
Classification Name and Number	Intervertebral body fusion device, 21 CFR §888.3080
Product Code	ODP
Predicate Devices	<p>Legally marketed predicate devices to which substantial equivalence is claimed:</p> <ul style="list-style-type: none"> <li>• Primary predicate: Stryker Spine AVS® AS Peek Spacers (K142251)</li> <li>• Additional Predicates:  <p>Orthovita Peek Spacer (K101171)</p> <p>Amendia Interbody Fusion Multi-level Cervical (K160924)</p> <p>Stryker Spine AERO®- C Cage System (K152532)</p> <p>Stryker Spine Tritanium® PL Cage (K152304, K162262)</p> </li> </ul>
Device Description	<p>The Stryker Spine Tritanium® C Anterior Cervical Cage is a hollow, ring shaped titanium alloy (Ti-6Al-4V) interbody fusion cage intended for use in the cervical spine. The cage consists of an open window for bone graft containment and has serrations on the superior and inferior surfaces of the cage for fixation. The cage is offered in a variety of footprints, heights, and lordotic angles to adapt to varying patient anatomies. The Tritanium® C Anterior Cervical Cage consists of a unique configuration of both solid and porous structures that are simultaneously built using Laser Rapid Manufacturing (LRM) method applying Stryker’s proprietary Tritanium® In-Growth Technology. The Tritanium® C Anterior Cervical Cage is provided sterile.</p>
Intended Use and Indications for Use	<p>The Stryker Spine Tritanium® C Anterior Cervical Cage is indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels from the C2 to T1 disc.</p>

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	<p>DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have six weeks of non-operative therapy.</p> <p>The Tritanium® C Anterior Cervical Cage System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach.</p> <p>The Tritanium® C Anterior Cervical Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine.</p>
Summary of the Technological Characteristics	<p>The subject Tritanium® C Anterior Cervical Cage and the predicates share similar design features:</p> <ul style="list-style-type: none"> <li>• Graft windows for packing autogenous or allogenic bone</li> <li>• Comparable heights, widths, depths, and lordotic angles</li> <li>• Serrations on the superior and inferior surfaces</li> <li>• Supplemental fixation</li> </ul>
Summary of Non-Clinical Testing	<p>Testing in compliance with: FDA’s June 12, 2007 “Class II Special Controls Guidance Document: Intervertebral Body Fusion Device” was performed for the Tritanium® C Anterior Cervical Cage and demonstrated substantially equivalent performance to the identified predicate devices.</p> <p>The following mechanical tests were performed:</p> <ul style="list-style-type: none"> <li>• Static Compression (per ASTM F2077)</li> <li>• Dynamic Compression (per ASTM F2077)</li> <li>• Static Compression Shear (per ASTM F2077)</li> <li>• Dynamic Compression Shear (per ASTM F2077)</li> <li>• Static Torsion (per ASTM F2077)</li> <li>• Dynamic Torsion (per ASTM F2077)</li> <li>• Expulsion (per ASTM F04-25-02-02 Draft)</li> <li>• Subsidence (per ASTM F2267)</li> <li>• Wear Debris Assessment</li> <li>• Impaction</li> </ul> <p>Characterization of the Physical Properties and Chemistry of the Tritanium® C Anterior Cervical Cage material testing</p>

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	<p>established that the porous surface design of the cage meets at minimum the requirements outlined in the:</p> <ul style="list-style-type: none"> <li>• FDA guidance documents: “Guidance Document for testing orthopedic implants with modified metallic surfaces apposing bone or bone cement [April 28, 1994]” , “Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses [January 16, 2003]”, and draft guidance for “Technical considerations for Additive Manufactured Devices [May 10, 2016]”</li> <li>• ASTM 1472-08: Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy (UNS R56400) for Surgical Implant Applications</li> </ul> <p>Characterization of the Mechanical Properties of the Tritanium® C Anterior Cervical Cage material was performed in accordance with the following standards:</p> <p>ASTM F1147-05: Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings</p> <p>ASTM F1044-05: Standard Test Method for Shear Testing of Calcium Phosphate and Metallic Coatings</p> <p>ASTM F1160-05: Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coating</p> <p>ASTM E8/E8M: Standard Test Methods for Tension Testing of Metallic Materials</p> <p>Electromechanical performance evaluation of additive manufactured Ti-6Al-4V alloy was also performed per ASTM F2129-15: Standard test method for conducting cyclic potentiodynamic polarization measurements to determine the corrosion susceptibility of small implant devices.</p> <p>Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 is used for pyrogenicity testing to achieve the</p>

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	Endotoxin limit of < 20EU/Device.
Conclusion	Based on the design features, the use of established well known materials, feature comparisons, indications for use, and results of the mechanical testing, the Tritanium® C Anterior Cervical Cage has demonstrated substantial equivalence to the identified predicate devices.