



Stryker  
Mr. Nikin Desai  
Regulatory Affairs Specialist  
2 Pearl Court  
Allendale, New Jersey 07401

January 18, 2018

Re: K173476  
Trade/Device Name: Tritanium® TL Curved Posterior Lumbar Cage  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: November 8, 2017  
Received: November 9, 2017

Dear Mr. Desai:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

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)

K173476

Device Name

Tritanium® TL Curved Posterior Lumbar Cage

Indications for Use (Describe)

The Stryker Spine Tritanium® TL cage is an intervertebral body fusion device indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the Tritanium TL Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Tritanium TL Cage is to be implanted via a posterior approach.

The Tritanium TL Cage is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral 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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## 510(k) Summary: Tritanium® TL Curved Posterior Lumbar Cage

Manufacturer/Submitter:	Stryker Spine 2 Pearl Ct. Allendale, NJ 07401
Contact Person :	Name: Nikin Desai Phone: (201) 749-8176 Fax: (201) 831-3000 Email:Nikin.Desai@stryker.com
Date Prepared:	11/08/2017
Trade Name:	Tritanium® TL Curved Posterior Lumbar Cage
Common Name:	Intervertebral body fusion device
Proposed Class:	Class II
Classification Name:	Intervertebral Body Fusion Device with Bone Graft, Lumbar (21 CFR §888.3080)
Product Code:	MAX
Predicate Devices:	<p>Primary Predicates:</p> <p style="text-align: right;">AVS® PL and TL PEEK Spacers (K151726)</p> <p>Additional Predicates:</p> <p style="text-align: right;">Tritanium® PL Posterior Lumbar Cage (K162262) Tritanium® C Anterior Cervical Cage (K171496)</p>
Device Description:	<p>The purpose of this submission is to introduce a curved posterior lumbar cage intended for use as an aid in lumbar spinal fixation.</p> <p>The Tritanium TL Intervertebral Body Fusion Cage is intended for use as an aid in lumbar spinal fixation. The cage is a curved implant that 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 cage is offered in a variety of lengths, heights and lordotic angles to adapt to a variety of patient anatomies. It has serrations on the superior and inferior surfaces designed for multidirectional fixation and to maximize surface area for endplate contact with the implant. The implants have a smooth, tapered leading edge to facilitate cage insertion into the intervertebral space. The implants have a central column spanning endplate to endplate for graft containment and to aid in fusion throughout the interbody cage.</p> <p>The implant is designed to be used with supplemental fixation cleared for use in the lumbosacral spine.</p> <p>The Tritanium TL cages are constructed from Titanium alloy: Ti-6Al-4V (ASTM F1472-08) and are provided sterile.</p>

510(k) Summary: Tritanium® TL Curved Posterior Lumbar Cage

<p>Indications for Use:</p>	<p>The Stryker Spine Tritanium® TL cage is an intervertebral body fusion device indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.</p> <p>DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.</p> <p>Additionally, the Tritanium TL Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.</p> <p>The Tritanium TL Cage is to be implanted via a posterior approach.</p> <p>The Tritanium TL Cage is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.</p>
<p>Summary of the Technological Characteristics</p>	<p>The Subject Tritanium TL Curved Posterior Lumbar Cage and the cleared Tritanium PL and C cages share similar material/material technology and the following design features:</p> <ul style="list-style-type: none"> <li>• Graft windows for packing autogenous or allogenic bone</li> <li>• Comparable heights, widths, lengths and lordotic angles</li> <li>• Serrations on the superior and inferior surfaces</li> <li>• Supplemental fixation</li> </ul>
<p>Summary of the Performance Data</p>	<p>Testing in compliance with:</p> <p>FDA’s June 12, 2007 “Class II Special Controls Guidance Document: Intervertebral Body Fusion Device” was performed for the subject Tritanium TL Cages and demonstrated substantially equivalent performance to the identified predicate devices. The following mechanical tests were performed:</p> <ul style="list-style-type: none"> <li>• Static and Dynamic Compression (per ASTM F2077-14)</li> <li>• Static and Dynamic Compression Shear (per ASTM F2077-14)</li> <li>• Static and Dynamic Torsion (per ASTM F2077-14)</li> <li>• Expulsion (per ASTM F04-25-02-02 Draft)</li> <li>• Subsidence (per ASTM F2267-04(2011) )</li> <li>• Wear Debris Assessment, and</li> <li>• Impaction</li> </ul> <p>Characterization of the Physical, Chemistry and Mechanical properties of the subject Tritanium TL Curved Posterior Lumbar Cage was established through</p>

510(k) Summary: Tritanium® TL Curved Posterior Lumbar Cage

Tritanium C Anterior Cervical Cage material testing which demonstrated that the porous surface design of the cage met at minimum the requirements outlined in the:

- 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]”
- ASTM 1472-08: Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy (UNS R56400) for Surgical Implant Applications
- ASTM F1147-05: Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
- ASTM F1044-05: Standard Test Method for Shear Testing of Calcium Phosphate and Metallic Coatings
- ASTM F1160-05: Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coating
- ASTM E8/E8M: Standard Test Methods for Tension Testing of Metallic Materials

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.

Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 is used for pyrogenicity testing to achieve the 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 TL Curved Posterior Lumbar Cage has demonstrated substantial equivalence to the identified predicate devices.