



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Stryker Spine  
Ms. Simona Voic  
Senior Project Manager, Regulatory Affairs  
2 Pearl Court  
Allendale, New Jersey 07401

November 19, 2015

Re: K152304  
Trade/Device Name: Tritanium® PL Cage  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: November 2, 2015  
Received: November 3, 2015

Dear Ms. Voic:

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.

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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 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 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 yours,

**Mark N. Melkerson -S**

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)

K152304

Device Name

Tritanium® PL Cage

Indications for Use (Describe)

The Stryker Spine Tritanium® PL 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® PL Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

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

The Tritanium® PL 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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<b>510(k) Summary as required by 21 CFR §807.92(c). Tritanium® PL Cage</b>	
Submitted by	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Simona Voic Sr. Project Manager, Regulatory Affairs Phone: 201-760-8033 Email: simona.voic@stryker.com
Date Prepared	August 13, 2015
Common Name	Intervertebral body fusion device
Trade Name	Tritanium® PL Cage
Proposed Class	Class II
Classification Name and Number	Intervertebral body fusion device, 21 CFR §888.3080
Product Code	MAX: Intervertebral Body Fusion Device with Bone Graft, Lumbar
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® PL and AVS® UniLIF™ (K1413163)</li> <li>• Additional predicate: Stryker Spine AccuLIF® TL and PL Cage(K143616)</li> <li>• Reference devices: Stryker Orthopaedics Triathlon® Tritanium® Tibial Baseplate (K123486) Stryker Orthopaedics Triathlon® Tritanium® Metal-Backed Patella (K132624) Stryker Orthopaedics Triathlon® Tritanium® Cone Augments (K143393) Stryker Spine VLIFT® Vertebral Body Replacement Device (K060506)</li> </ul>
Device Description	The Tritanium® PL Intervertebral Body Fusion Cage is intended for use as an aid in lumbar spinal fixation. The cage is a hollow, rectangular 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, widths and

<b>510(k) Summary as required by 21 CFR §807.92(c). Tritanium® PL Cage</b>	
	<p>lordotic angles to adapt to a variety of patient anatomies. It has serrations on the superior and inferior porous surfaces of the implant for fixation, an ergonomically shaped anterior edge, and a flat posterior edge.</p> <p>The implant is designed to be used with supplemental fixation cleared for use in the lumbosacral spine.</p> <p>The Tritanium® PL cages are constructed from Titanium alloy: Ti-6Al-4V (ASTM F1472-08) and are provided sterile.</p>
Intended Use and Indications for Use	<p>The Stryker Spine Tritanium® PL 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® PL Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.</p> <p>The Tritanium® PL Cage is to be implanted via a posterior approach.</p> <p>The Tritanium® PL Cage is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.</p>
Summary of the Technological Characteristics	<p>The subject Tritanium® PL Cage and the predicates share similar design features:</p> <ul style="list-style-type: none"> <li>• Graft windows for packing autogenous bone</li> <li>• Serrations on the superior and inferior surfaces</li> <li>• Comparable heights, widths, depths, and lordotic angles, material</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® PL 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> </ul>

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	<ul style="list-style-type: none"> <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® PL Cage material testing 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] “ and “Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses [January 16, 2003]”, and</li> <li>• ASTM 1472-08</li> </ul> <p>Characterization of the Mechanical Properties of the Tritanium® PL Cage material was performed in accordance with the following standards: ASTM F1147-05, ASTM F1044-05, ASTM F1160-05, and ASTM E8/E8M. Electromechanical performance evaluation of additive manufactured Ti-6Al-4V alloy was also performed per ASTM F2129-09.</p>
<b>Conclusion</b>	<p>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® PL Cage has demonstrated substantial equivalence to the identified predicate devices. Furthermore, the characteristics of the porous surface design of the subject device are substantially equivalent based on meeting the acceptance criteria of the guidance document and all referenced materials presented in this application.</p>