DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 21, 2019

Stryker Spine
Ms. Deirdre Jayko
Regulatory Affairs Associate
2 Pearl Court
Allendale, New Jersey 07401

Re: K160955
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: May 2, 2016
Received: May 3, 2016

Dear Ms. Jayko:

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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160955

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.

510(k) Summary as required by 21 CFR §807.92(c). Tritanium® PL Cage	
Submitted by	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Deirdre Jayko Regulatory Affairs Associate Phone: 201-749-8339 Email: deirdre.jayko@stryker.com
Date Prepared	June 30, 2016
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	Legally marketed predicate devices to which substantial equivalence is claimed: • Primary predicate Stryker Spine Tritanium® PL Cage (K152304)
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 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. The implant is designed to be used with supplemental fixation cleared for use in the lumbosacral spine. The Tritanium® PL cages are constructed from Titanium alloy: Ti-6Al-4V (ASTM F1472-08) and are provided sterile.
Intended Use and Indications for Use	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

510(k) Summary as required by 21 CFR §807.92(c). Tritanium® PL Cage	
	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.
Summary of the Technological Characteristics	The subject Tritanium® PL Cage shares identical materials, design features, and fundamental scientific technologies as the predicate Tritanium® PL Cage.
Summary of Non-Clinical Testing	The scope of this Traditional 510(k) submission includes device modifications for the Tritanium® PL Cages which were previously cleared under K152304. Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 is used for pyrogenicity testing to achieve the Endotoxin limit of < 20EU/Device. As there is no change in fit, form, or function of the device compared with the Tritanium® PL Cage previously cleared under K152304, no additional mechanical testing was performed. No validation or verification data is presented in this submission.
Conclusion	The Tritanium® PL Cage is identical to the previously cleared predicate Tritanium® PL Cage with respect to design features, intended use/indications for use, technological characteristics, material, and basic principles of operation. The purpose of this submission is to provide a summary of device modifications for the Tritanium® PL Cages which were previously cleared under K152304.These modifications have no impact on the form, fit, or function of the device as compared with the previously cleared Tritanium® PL Cage. There is no change to intended use/indications for use. The modifications do not present any new issues of safety or effectiveness.