Stryker Spine
Mr. Travis Catania
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

July 18, 2018

Re: K181014
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 18, 2018
Received: May 21, 2018

Dear Mr. Catania:

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 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter -S

for
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)*

K181014

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: Tritanium® PL Cage	
Submitter:	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person :	Name: Travis Catania Phone: (201) 749-8038 Fax: (201) 962-4070 Email: Travis.Catania@stryker.com
Date Prepared:	5/23/2018
Trade Name:	Tritanium® PL Cage
Common Name:	Intervertebral body fusion device
Proposed Class:	Class II
Classification Name:	Intervertebral Body Fusion Device (21 CFR §888.3080)
Product Code:	MAX: Intervertebral Body Fusion Device with Bone Graft, Lumbar
Predicate Devices:	Primary Predicate: Tritanium® PL Cage(K160955) Additional Predicates: N/A Reference Devices: N/A
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 footprints 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.

510(k) Summary: Tritanium® PL Cage	
Intended 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 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 the same materials, fundamental scientific technologies, and design characteristics as the predicate Tritanium® PL Cages. The purpose of this submission is to introduce and summarize the proposed design changes to the Tritanium® PL Cages, which retain the previously FDA cleared indications / intended use and mode of operation as presented in the previous 510(k) submission, K160955.
Summary of the Performance Data	The Stryker Spine Tritanium® PL Cage, with the incorporation of the proposed design changes, has demonstrated substantial equivalence to the predicate device. The Engineering Analysis, which included two FEAs, has demonstrated that the proposed design changes do not adversely affect the performance of the Tritanium® PL Cage and do not represent a new, worst case scenario in any of the test methods presented in the predicate submission including: • Static and Dynamic Compression Shear (per ASTM F2077-14) • Static and Dynamic Torsion (per ASTM F2077-14) • Static and Dynamic Compression (per ASTM F2077-14) • Subsidence (per ASTM F2267-04) • Expulsion (per ASTMF04-25-02-02 (Draft)-2000) • Wear Debris Analysis • Impaction No additional performance data is provided as part of this submission.
Conclusion	Verification and validation activities demonstrated that all relevant acceptance criteria were met. The modified device is substantially equivalent to the predicate Tritanium PL® Cage.