July 25, 2019

Stryker Spine
Deirdre Jayko
Senior Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K183249
Trade/Device Name: Tritanium® X PL Expandable Posterior Lumbar Cage, Tritanium® X TL Expandable Curved Posterior Lumbar Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 3, 2019
Received: July 5, 2019

Dear Deirdre 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Melissa Hall, M.S.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K183249

Device Name
Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage

Indications for Use *(Describe)*
The Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are intended for intervertebral body fusion with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment.

Additionally, the Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are always to be used with supplemental internal spinal fixation. Additionally, the Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion.

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® X PL Expandable Posterior Lumbar Cage & Tritanium® X TL Expandable Curved Posterior Lumbar Cage	
Manufacturer/Submitter:	Stryker Spine 2 Pearl Ct. Allendale, NJ 07401
Contact Person :	Name: Deirdre Jayko Phone: (201) 749-8339 Email: deirdre.jayko@stryker.com
Date Prepared:	11/20/2018
Trade Name:	Tritanium® X PL Expandable Posterior Lumbar Cage Tritanium® X TL Expandable 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:	Primary Predicates: AVS® PL Spacers (K151726) Additional Predicates: Tritanium® PL Posterior Lumbar Cage (K181014) Tritanium® TL Posterior Curved Lumbar Cage (K173476) Globus Rise® Spacers (K171848)
Device Description:	The purpose of this submission is to introduce an expandable posterior lumbar cage intended for use as an aid in lumbar spinal fixation. The expandable Tritanium® X PL Expandable Posterior Lumbar Cage and the Tritanium® X TL Expandable Curved Posterior Lumbar Cage (also referred to as Tritanium X Cages) are Intervertebral Body Fusion Cages intended for use as an aid in lumbar spinal fixation. The TL cages are crescent shaped, and the PL cages are straight shaped. These cages consist 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 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 graft windows spanning endplate to

510(k) Summary: Tritanium® X PL Expandable Posterior Lumbar Cage & Tritanium® X TL Expandable Curved Posterior Lumbar Cage	
	endplate for graft containment and to aid in fusion throughout the interbody cage. The implant is designed to be used with supplemental fixation cleared for use in the lumbosacral spine. The Tritanium X cages are constructed from Titanium alloy: Ti-6Al-4V (ASTM F1472-08), Stainless Steel: 316 LVM (ASTM F138-08), and Silicone Rubber, and are provided sterile.
Indications for Use:	The Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are intended for intervertebral body fusion with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment. Additionally, the Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are always to be used with supplemental internal spinal fixation. Additionally, the Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion.
Summary of the Technological Characteristics	The subject Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are hydraulically expandable interbody fusion devices. The subject devices share technological characteristics with the cited predicate devices and do not raise any new questions of safety and effectiveness. The below characteristics are shared between the subject and predicate devices: • Graft windows for packing autogenous or allogenic bone • Comparable heights, widths, lengths, and lordotic angles • Serrations on the superior and inferior surfaces

510(k) Summary: Tritanium® X PL Expandable Posterior Lumbar Cage & Tritanium® X TL Expandable Curved Posterior Lumbar Cage	
	• Indicated for use with supplemental fixation • Expandable in-situ
Summary of the Performance Data	Testing in compliance with: FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the subject Tritanium X Cages and demonstrated substantially equivalent performance to the identified predicate devices. The following mechanical tests were performed: • Static and Dynamic Compression (per ASTM F2077) • Static and Dynamic Compression Shear (per ASTM F2077) • Static and Dynamic Torsion (per ASTM F2077) • Expulsion • Subsidence (per ASTM F2267-04) • Wear Debris Assessment • Impaction Characterization of the Physical, Chemical, and Mechanical properties of the subject Tritanium X Cage was established through 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 guidance for "Technical Considerations for Additive Manufactured Devices [December 5, 2017]" • 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

510(k) Summary: Tritanium® X PL Expandable Posterior Lumbar Cage & Tritanium® X TL Expandable Curved Posterior Lumbar Cage	
	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 X Cage has demonstrated substantial equivalence to the identified predicate devices.