



Stryker Corporation
Jamie Wilson
Sr. Staff Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

April 15, 2020

Re: K200613

Trade/Device Name: 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: March 19, 2020
Received: March 19, 2020

Dear Jamie Wilson:

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
Brent Showalter, Ph.D.
Assistant Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K200613

Device Name

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 TL Expandable, Curved, Posterior Lumbar Cage

Submitter:	Stryker Spine 2 Pearl Ct. Allendale, NJ 07401
Contact Person :	Name: Jamie Wilson, RAC Phone: 832-498-6935 Email: Jamie.wilson1@stryker.com
Date Prepared:	March 19, 2020
Trade Name:	Tritanium® X TL Expandable Curved Posterior Lumbar Cage
Common Name:	Intervertebral body fusion device
Proposed Class:	Class II
Classification Name:	Intervertebral Fusion Device with Bone Graft, Lumbar (21 CFR §888.3080)
Product Code:	MAX
Predicate Devices:	Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage (K183249)
Device Description:	The purpose of this submission is to introduce an additional cage size to the range of available Tritanium TL cages. The dimensions of the subject device are identical to the predicate TL cages (12mm width; 32mm length) but with a height of 8-10mm (based on expansion). The current range of Tritanium TL cages currently range in heights from 9-13mm.
Indications for Use:	<p>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.</p> <p>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.</p> <p>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.</p>

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

<p>Summary of the Technological Characteristics</p>	<p>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 device shares 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:</p> <ul style="list-style-type: none">• Graft windows for packing autogenous or allogenic bone• Serrations on the superior and inferior surfaces• Indicated for use with supplemental fixation• Expandable in-situ <p>There are no changes to the fundamental technological characteristics of the identified predicate devices in this submission.</p>
<p>Summary of the Performance Data</p>	<p>A risk review was conducted on existing verification and validation data for the Tritanium X system relative to the addition of the 8mm implant. The results of this risk review indicated that there would be no impacts to safety or effectiveness of the system by including this device.</p> <p>The following mechanical tests were performed:</p> <ul style="list-style-type: none">• Subsidence testing conducted per ASTM F2267-04(2018)• Impaction testing
<p>Conclusion</p>	<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® X TL Expandable Curved Posterior Lumbar Cage has demonstrated substantial equivalence to the identified predicate devices.</p>