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

March 5, 2015

Stryker Corporation
Mr. Aakash Jain
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K143616
Trade/Device Name: AccuLIF® TL and PL Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 18, 2014
Received: December 19, 2014

Dear Mr. Jain:

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" (21CFR 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)*
K143616

Device Name
AccuLIF® TL and PL Cage

Indications for Use *(Describe)*

The AccuLIF TL and PL Cages are indicated 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 AccuLIF TL and PL Cages can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AccuLIF TL and PL Cages are always to be used with supplemental internal spinal fixation. Additionally, the AccuLIF TL and PL Cages 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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Stryker Spine AccuLIF® TL and PL Cage 510(k) Summary	
Submitter	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person	Aakash Jain Regulatory Affairs Specialist Phone: 201-760-8074 Fax: 201-962-4074 E-mail: aakash.jain@stryker.com
Date Prepared	March 3, 2015
Trade Name	AccuLIF® TL and PL Cage
Common Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Proposed Class	Class II
Additional Classification	
• Codification	21 CFR § 888.3080
• Name	Intervertebral body fusion device
Product Codes	MAX
Predicate Devices	The AccuLIF® TL and PL Cage was shown to be substantially equivalent to the device listed below: • Primary Predicate: Stryker Spine, ACCULIF® TL and PL Cage K143163 • Additional Predicate: Medtronic, Capstone Spinal System, K123027
Device Description	The AccuLIF TL and PL Cage device is an expandable interbody fusion cage manufactured from implant grade Titanium alloy (TI6AI4V ELI) as per ASTM F136-08, Stainless Steel (316 LVM) as per ASTM F138-08, and Silicone Rubber (MED-4870). As with the predicate expandable AccuLIF TL and PL Cage devices, the device is inserted in unexpanded state with a delivery handle and expanded in-situ to the required height via 2 hydraulic cylinder and piston arrangements using a hydraulic system comprising disposable flexible expansion tubing set and inflation syringe. The device automatically locks at 1mm increments as it expands. The AccuLIF TL and PL Cage come in a variety of sizes, shapes, and lordotic angles to accommodate patient anatomy. The AccuLIF TL and PL Cage system comprises a packaged sterile AccuLIF implant, an instrument tray, and a packaged sterile Tubing Assembly. Within the TL or PL instrument trays are an inserter, pressure syringe, slap hammer, graft insertion cannula, graft insertion pusher, bone graft block, and TL or PL distractor trials. Additional instruments supplement the instrument trays.
Indications for Use	The AccuLIF TL and PL Cages are indicated 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 AccuLIF TL and PL Cages can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The AccuLIF TL and PL Cages are always to be used with supplemental internal spinal fixation. Additionally, the AccuLIF TL and PL Cages 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 Technological Characteristics	The subject AccuLIF® TL and PL Cage and the predicate devices were shown to be substantially equivalent based on material, design, and mechanical performance and indications.
Summary of the Performance Data	Published clinical data for lumbar interbody fusion devices similar to the Stryker Spine AccuLIF TL and PL devices that are the subject of this submission was provided in support of this application. The published clinical outcomes demonstrated that the use of the lumbar interbody fusion procedures to treat patients diagnosed with degenerative scoliosis above does not adversely affect performance of the system and does not represent a new worst case scenario. No changes were made to the existing devices; therefore, no additional implant testing was required or performed.
Conclusion	The design features, materials used, manufacturing, and sterilization methods are identical to the previously cleared ACCULIF® TL and PL Cage with the exception of expanding the indications to include the degenerative scoliosis. The additional indication is identical to Medtronic Capstone Spinal System. Based on information provided, the subject device has been determined to be substantially equivalent to the predicate devices.