510(k) Summary: AccuLIF® TL and PL Cage	
Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Kristen Meany, MS, CQA, RAC Project Manager, Regulatory Affairs Phone: 201-760-8070 Fax: 201-962-4070 Email: kristen.meany@stryker.com
Date Prepared	June 18, 2014
Trade Name	AccuLIF® TL and PL Cage
Common Name	Lumbar Interbody Device
Proposed Class	Class II
Classification Name and Number	Intervertebral body fixation device 21 CFR § 888.3080
Product Code	MAX
Predicate Devices	AccuLIF TL and PL Cage (K132505)
Device Description	The AccuLIF® TL and PL Cage device is an expandable interbody fusion cage manufactured from implant grade Titanium alloy (TI6Al4V ELI) as per ASTM F136-08, Stainless Steel (316 LVM) as per ASTM F138-08, and Silicone Rubber (MED-4870). 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 arrangement using a hydraulic system comprising disposable flexible expansion tubing set and inflation syringe. The device locks in 1mm increments as it expands. The AccuLIF TL and PL Cage comes in three sizes which are expandable from 6mm to 9mm, from 8mm to 12mm, and from 10mm to 16mm in 1mm increments. As well each size comes in two shapes, crescent and straight and each shape comes in two different footprints 11mm x 25mm and 13mm x 25mm for the crescent shape and 11mm x 22mm and 11mm x 25mm for the straight shape. Also the TL crescent shape comes in an 8 degree lordotic model as well as a 0 degree model for a total of 18 TL and PL models. The device has fixation ridges on the top and bottom surface. It also has a graft opening window which extends from the bottom surface to the top surface. The device has a proximal boss which has a threaded connection port for connecting to the inserter and a fluid port for transporting the expansion fluid. The AccuLIF TL and PL Cage system comprises a packaged sterile AccuLIF implant, an instrument tray, and a packaged sterile Unlock 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

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	instruments supplement the instrument trays.
Intended Use	Intervertebral Body Fusion Device: The AccuLIF TL and PL Cage are indicated for intervertebral body fusion with autogenous bone graft material 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. 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 autogenous bone graft.
Summary of the Technological Characteristics	The purpose of this 510(k) is to introduce modifications to the AccuLIF Pressure Syringe. There have been no changes to the AccuLIF TL and PL Cage implants as a result of the proposed modifications to the AccuLIF Pressure Syringe. The AccuLIF TL and PL Cage and the predicate device are both expandable, have similar design features, are both used in the anterior column of the spine, and both use Titanium alloy as the main device material. The modified AccuLIF Pressure Syringe continues to function as the predicate AccuLIF Pressure Syringe – to pressure saline in order to expand the AccuLIF TL and PL Cage implants. Although there are minor differences between the modified device and its predicate device, namely the changes being made to the AccuLIF Pressure Syringe, those differences do not raise new questions of safety or efficacy.
Summary of the Performance Data	Design verification testing was conducted to assess the instrument modifications. Specifically, the AccuLIF Pressure Syringe was tested after 20 cycles of simulated cleaning, sterilization and insertion/withdrawal impact, to verify that the modifications to the instrument did not adversely affect the intended function of the device. Specifically, the instrument and o-rings were observed for damage and the pressure delivered by the instrument was examined to ensure the appropriate pressure continues to be delivered to the AccuLIF TL or PL Cage. Modifications to the AccuLIF Pressure Syringe have been verified to meet the design input requirements and showed no signs of deterioration or malfunction after 20 simulated cleanings, sterilizations and uses. The non-clinical test results demonstrate that any minor differences do not impact device performance as compared to the predicate device.

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Conclusions	The modified accessory to the AccuLIF TL and PL Cage has identical indications, technological characteristics, and principles of operation as its predicate. The non-clinical test results demonstrate that any minor differences do not impact device performance as compared to the predicate. Thus, the modified device was shown to be substantially equivalent to the AccuLIF TL and PL Cage (K132505).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 16, 2014

Stryker Spine
Kristen Meany, MS, CQA, RAC
Project Manager, Regulatory Affairs
2 Pearl Court
Allendale, New Jersey 07401

Re: K141217
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: June 18, 2014
Received: June 19, 2014

Dear Ms. Meany:

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,

Ronald P. Jean -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)*
K141217

Device Name
AccuLIF(R) TL and PL Cage

Indications for Use *(Describe)*

Intervertebral Body Fusion Device: The AccuLIF TL and PL Cages are indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two continuous 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 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment.

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 autogenous bone graft.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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