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510(k) Summary
Avenue® L Interbody Fusion System

JUL 26 2012

Owner's Name & Address:
LDR Spine USA
13785 Research Blvd. Suite 200
Austin, TX 78750

Contact Person:
Bradley W. Strasser
Regulatory Affairs Project Manager
Phone: (512) 344-3395
Fax: (512) 795-8306
Email: bradstrasser@ldrspine.com

Date:
July 26, 2012

Trade Name:
LDR Spine USA Avenue® L Interbody Fusion System

Common Name:
Intervertebral Body Fusion Device

Classification:
OVD 888.3080- Intervertebral Fusion Device with Integrated Fixation, Lumbar

Predicate Devices:
LDR Spine ROI-A Implant System; K082262, February 02, 2009; K090507, June 25, 2009; K110327, September 30, 2011
LDR Spine ROI-T Implant System; K082262, February 02, 2009
Globus InterContinental® Plate-Spacer; K103382, May 20, 2011

Device Description
The Avenue L Interbody Fusion System is intended for use as an interbody fusion device in the lumbar spine. The device consists of intervertebral cages manufactured from medical grade PEEK OPTIMA® LT1 (ASTM F2026) with embedded titanium alloy markers (ASTM F136) to facilitate visibility in x-ray imaging. The Avenue L is available with VerteBRIDGE titanium alloy anchoring plates which facilitate fixation to the superior and inferior vertebra, in addition to supplemental fixation. The Avenue L is designed for placement using a lateral surgical approach.

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Indications for Use:

The Avenue® L Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with or without integrated fixation and must be used in conjunction with posterior supplemental fixation (e.g. pedicle screws). The device system is intended to be used with autograft to facilitate fusion.

Non-Clinical Testing:

Testing was comprised of subsidence, static axial and shear compression, static torsion, dynamic axial compression and torsion (per ASTM F2077), expulsion (per ASTM F-04.25.02.02), wear debris analysis (per ASTM F1877), and cadaveric evaluations (including flexion/extension and lateral bending fatigue). The results of this testing demonstrate that the performance of the LDR Spine Avenue L system is substantially equivalent to the predicate devices.

Clinical Testing:

Clinical testing was not required to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

LDR Spine USA, Incorporated
% Mr. Bradley W. Strasser
Regulatory Affairs Project Manager
13785 Research Boulevard, Suite 200
Austin, Texas 78750

JUL 26 2012

Re: K113285
Trade/Device Name: LDR Spine Avenue® L Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: July 23, 2012
Received: July 24, 2012

Dear Mr. Strasser:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K113285

Device Name: LDR Spine Avenue® L Interbody Fusion System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113285