DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 11, 2015

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

Re: K142645
Trade/Device Name: Avenue T® TLIF Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: May 11, 2015
Received: May 12, 2015

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 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

INDICATIONS FOR USE

510(k) Number (if known): K142645

Device Name: Avenue® T TLIF Cage

Indications for Use:

The Avenue® T TLIF Cage 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 or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Avenue T TLIF Cage is designed for use with or without integrated fixation and must be used in conjunction with supplemental fixation cleared by FDA for use in the lumbar spine. The device is implanted via a transforaminal approach and intended for use with autograft to facilitate fusion.

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

510(k) Summary

Owner's Name & Address:	LDR Spine USA 13785 Research Blvd. Suite 200 Austin, TX 78750
Contact Person:	Bradley W. Strasser, RAC Manager, U.S. Regulatory Affairs Phone: (512) 344-3395 Fax: (512) 795-8306 Email: brad.strasser@ldrspine.com
Date:	June 09, 2015
Trade Name:	Avenue® T TLIF Cage
Common Name:	Intervertebral body fusion device with integrated fixation, lumbar
Panel:	Orthopedic
Product Code:	OVD, MAX
Classification:	Class II, 21 CFR 888.3080
Primary Predicate Device:	CAPSTONE® Spinal System, Medtronic Sofamor Danek USA, Inc. (K133650, cleared December 20, 2013)
Additional Predicate Devices:	Avenue® L Interbody Fusion Cage, LDR Medical SAS (K113285, cleared July 26, 2012)

Device Description:

The Avenue T TLIF (Transforaminal Lumbar Interbody Fusion) Cage system is comprised of various size interbody cages, integrated fixation anchoring plates (VerteBRIDGE® Plating), and associated instrumentation. The Avenue T cage is intended for use as an intervertebral body fusion cage in the anterior column of the lumbar spine. The Avenue T cage is designed to be implanted obliquely via a transforaminal approach. The cages feature rows of uni-directional teeth on the superior and inferior surfaces to aid stability and a tapered bullet-shaped tip to ease insertion. The Avenue T cages have a hollow central cavity to contain autogenous bone graft for fusion.

After cage placement, the VerteBRIDGE integrated fixation anchoring plates may be inserted into the cage to provide further stability and fixation. The VerteBRIDGE anchoring plates pass

through the cage via slots and lodge firmly into the superior and inferior vertebral endplates. The VerteBRIDGE anchoring plates lock into the Avenue T cages via an integral titanium locking pin.

The Avenue T cage is manufactured from PEEK-OPTIMA® LT1 with embedded ASTM F136 titanium alloy radiographic markers and anchoring plate locking pins. The VerteBRIDGE anchoring plates are manufactured from ASTM F136 titanium alloy.

The Avenue T cages are designed in a variety of length, height, and lordosis combinations to best fit varying patient anatomies.

Indications for Use:

The Avenue T TLIF Cage 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 or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Avenue T TLIF Cage is designed for use with or without integrated fixation and must be used in conjunction with supplemental fixation cleared by FDA for use in the lumbar spine. The device is implanted via a transforaminal approach and intended for use with autograft to facilitate fusion.

Non-Clinical Performance Data:

Non-clinical performance bench testing conducted to support substantial equivalence for the Avenue T TLIF Cage included:

- Static and dynamic compression testing per ASTM F2077-11
- Static and dynamic compressive shear testing per ASTM F2077-11
- Static and dynamic torsion testing per ASTM F2077-11
- Subsidence testing per ASTM F2267-04
- Static cage expulsion testing
- Static anchoring plate expulsion testing
- Wear testing & debris analysis

Additionally, an implantation study was conducted as part of this 510(k) and assessment of the subject device.

The results of this non-clinical testing demonstrate that the strength of the Avenue T TLIF Cage is sufficient for its intended use and is therefore substantially equivalent to legally marketed predicate devices.

Clinical Performance Data:

Clinical testing was not required to demonstrate substantial equivalence.

Basis of Substantial Equivalence:

The Avenue T TLIF Cage system is substantially equivalent to the predicate devices based on intended use and indications for use. The differences in technological characteristics do not raise different questions of safety and effectiveness and the scientific data from assessment of these characteristics demonstrate that the subject device is fit for its intended use and comparable to predicate devices. Therefore, the Avenue T TLIF Cage overall is substantially equivalent to the predicate devices.