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

September 28, 2016

LDR Spine USA, Inc.
Mr. Brad Strasser
Manager, U.S. Regulatory Affairs
13785 Research Blvd, Suite 200
Austin, Texas 78750

Re: K161173
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
Dated: September 1, 2016
Received: September 2, 2016

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 Parts 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,

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)*
K161173

Device Name
Avenue® T TLIF Cage

Indications for Use *(Describe)*
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 and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Contact Person: Brad Strasser, RAC
Manager, U.S. Regulatory Affairs
Phone: (512) 344-3395
Fax: (512) 795-8306
Email: brad.strasser@zimmerbiomet.com

Date: September 27, 2016

Trade Name: Avenue® T TLIF Cage

Common Name: Intervertebral body fusion device with integrated fixation, lumbar

Panel: Orthopedic

Product Code: OVD

Classification: Class II, 21 CFR 888.3080

Primary Predicate Device: K142645 Avenue T TLIF Cage
Additional Predicates: K153495 Avenue T TLIF Cage

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 or allogenic 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 locking pin.

The Avenue T cage is manufactured from PEEK-OPTIMA® LT1 with embedded ASTM F136 titanium alloy radiographic markers and ASTM F2063 wrought nickel-titanium shape memory alloy anchoring plate locking pins. The VerteBRIDGE anchoring plates are manufactured from ASTM F136 titanium alloy.

The Avenue T cages are designed in 30mm and 34mm lengths, 8mm to 19mm heights, and an 11mm width with lordosis angles ranging from 0° to 9°.

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 and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion.

Non-Clinical Performance Data:

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

- Finite Element Analysis
- Dynamic compressive shear testing per ASTM F2077-11
- Static anchoring plate expulsion testing
- Wear testing & debris analysis
- Corrosion testing
- Limulus Amebocyte Lysate (LAL) endotoxin testing

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

Clinical Performance Data:

Clinical testing was not required to demonstrate substantial equivalence.

Comparison of Technological Characteristics:

The Avenue T TLIF Cage system is substantially equivalent to the predicate devices based on intended use and indications for use. There are no differences in fundamental scientific technology from the predicate device. Minor differences in technological characteristics were assessed via a risk analysis and verification and validation activities. These activities demonstrated that the technological differences between the subject and predicate devices do not raise any new questions of safety and effectiveness, and the Avenue T TLIF Cage is substantially equivalent to the predicate.

Conclusion:

In conclusion, non-clinical testing has demonstrated the subject Avenue T TLIF Cage is equivalent to the predicate device in terms of bench performance and conformance with endotoxin limits. Verification and validation activities performed in conjunction with risk analysis demonstrate the device does not raise any issues of safety and effectiveness. Therefore, the Avenue T TLIF Cage overall is substantially equivalent to the predicate device.