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

March 31, 2016

LDR Spine USA
% Mr. Justin Eggleton
Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisors, LLC
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

Re: K153495
Trade/Device Name: Avenue® L Lateral Lumbar Cage, Avenue® T TLIF Cage System, ROI-A® ALIF Cage System, ROI-T® Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVD, MQP
Dated: February 23, 2016
Received: February 24, 2016

Dear Mr. Eggleton:

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,

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)*
K153495

Device Name
Avenue® L Lateral Lumbar Cage

Indications for Use *(Describe)*
The Avenue® L Lateral Lumbar 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. 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 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.

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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)*
K153495

Device Name
Avenue® T TLIF Cage System

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)

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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153495

Device Name
ROI-A® ALIF Cage System

Indications for Use *(Describe)*
The ROI-A® ALIF 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 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 supplemental fixation and 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)

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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)*
K153495

Device Name
ROI-T® Implant System

Indications for Use *(Describe)*
The ROI-T® Implant 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 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 supplemental fixation and with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion.

When used as a vertebral body replacement device, the ROI-T® Implant System is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a partial vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. Supplemental internal fixation is required to properly utilize the system. These devices are intended to be used with autograft or allograft bone.

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)

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510(k) Summary

Device Trade Name:
Avenue® L Lateral Lumbar Cage
Avenue® T TLIF Cage System
ROI-A® ALIF Cage System
ROI-T® Implant System

Manufacturer:
LDR Spine USA
13785 Research Boulevard, Suite 200
Austin, TX 78750
Phone: (512) 344-3333

Contact:
Mr. Brad Strasser
Manager, U.S. Regulatory Affairs
LDR Spine USA

Prepared by:
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1331 H Street NW, 12th Floor
Washington, DC 20005
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Date Prepared:
March 30, 2016

Classifications:
21 CFR §888.3080, Intervertebral body fusion device
21 CFR §888.3060, Spinal intervertebral body fixation orthosis

Class:
II

Product Codes:
MAX, OVD, MQP

Indications For Use:

Avenue® L Lateral Lumbar Cage

The Avenue® L Lateral Lumbar 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. 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 and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion.

Avenue® T TLIF Cage System

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.

ROI-A® ALIF Cage System

The ROI-A® ALIF 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 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 supplemental fixation and with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion.

ROI-T® Implant System

The ROI-T® Implant 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 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 supplemental fixation and with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion.

When used as a vertebral body replacement device, the ROI-T Implant System is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a partial vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. Supplemental internal fixation is required to properly utilize the system. These devices are intended to be used with autograft or allograft bone.

Device Description:
The Avenue L Lateral Lumbar Cage 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 Lateral Lumbar Cage is available with VerteBRIDGE® titanium alloy anchoring plates which facilitate fixation to the superior and inferior vertebra, which may be used in addition to supplemental fixation. The Avenue L Lateral Lumbar Cage is designed for placement using a lateral surgical approach.

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 TLIF Cage System is intended for use as an intervertebral body fusion cage in the anterior column of the lumbar spine. The Avenue T TLIF Cage System 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 TLIF Cage System 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 TLIF Cage System via an integral locking pin.

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

The ROI-A ALIF Cage System is intended for use as an interbody fusion device in the lumbar spine. The device is manufactured from medical grade PEEK OPTIMA LT1 in accordance with ASTM F2026 and has tantalum markers conforming to ASTM F560 embedded in the implant to facilitate visibility in x-ray imaging. The subject device is designed for placement using either an anterior or anterolateral approach. The ROI-A ALIF Cage System implants feature two slots which allow for use with device-specific integrated fixation – the ROI-A VerteBRIDGE anchoring plate. The ROI-A ALIF Cage System VerteBRIDGE anchoring plate is made of titanium alloy (Ti-6Al-4V, ASTM F136) and can be inserted to obtain fixation to the vertebral bone and create a standalone lumbar interbody fusion cage construct.

The ROI-T Implant System consists of crescent shaped cages in a variety of heights and lordotic angles. The ROI-T Implant System implant has an enclosed graft space design. The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and to prevent movement of the implants. The ROI-T Implant System PEEK cages are designed to be inserted via a transforaminal approach. The ROI-T Implant System cages are manufactured from

medical grade PEEK OPTIMA LT1 in accordance with ASTM F2026 and has tantalum markers (ASTM F560) embedded in the implant to facilitate visibility during x-ray imaging.

The purpose of the subject 510(k) was to expand the indications to include use with allograft in the lumbar spine.

Predicate Devices:
Primary Predicate:
Avenue® L Lateral Lumbar Cage (K113285)
Avenue® T TLIF Cage (K142645)
ROI-A® ALIF Cage System (K110327)
ROI-T® Implant System (K082262)

Additional Predicates:
Orthofix FORZA® Spacer System (K152475)
Centinel Spine STALIF TT™, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™ (K150643).

Comparison of Technological Characteristics
The predicate Avenue L Lateral Lumbar Cage, Avenue T TLIF Cage System, ROI-A ALIF Cage System and ROI-T Implant System (K113285, K142645, K110327, K090507, and K082262), Orthofix FORZA® Spacer System (K152475) and Centinel Spine STALIF TT™, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™ (K150643) are similar in indications for use, intended use, design, material, and performance, and are all cleared devices.

Summary of Clinical Information
A comprehensive clinical literature review was conducted to assess any additional safety concern for the use of this device with the use of allograft in the lumbar spine. The review of the literature concluded that there were no additional risks due to the modification of indications for this device and that the devices was substantially equivalent to the predicate devices.

Conclusion:
This 510(k) was submitted on behalf of the Avenue L Lateral Lumbar Cage, Avenue T TLIF Cage System, ROI-A ALIF Cage System and ROI-T Implant System to expand the indications for use to include use with allograft in lumbar interbody fusions. Substantial equivalence with respect to indications for use, intended use, design, and performance was determined in response to sufficient comparisons to a predicate device.