



Food and Drug Administration
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Silver Spring, MD 20993-0002

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

September 17, 2015

Re: K150765

Trade/Device Name: LDR Spine ROI-C Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: August 20, 2015
Received: August 21, 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)

K150765

Device Name

LDR Spine ROI-C Cervical Cage System

Indications for Use (Describe)

The LDR Spine ROI-C Cervical Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The LDR Spine ROI-C Cervical Cage System is to be used with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft and placed via an open, anterior approach. Supplemental internal fixation is required to properly utilize this system.

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.

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510(k) Summary

Device Trade Name: LDR Spine ROI-C Cervical Cage System

Manufacturer: LDR Spine USA
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Date Prepared: September 15, 2015

Classifications: 21 CFR §888.3080, Intervertebral body fusion device.

Class: II

Product Codes: OVE

Indications For Use:

The LDR Spine ROI-C Cervical Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The LDR Spine ROI-C Cervical Cage System is to be used with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft and placed via an open, anterior approach. Supplemental internal fixation is required to properly utilize this system.

Device Description:

The LDR Spine ROI-C Cervical Cage System consists of 'D' shaped blocks in a variety of heights and length x width configurations, and features an enclosed graft space. Lateral rows of teeth are present on both the caudal and cephalic surfaces of the device. The flat of the 'D' shape represents the anterior most portion of the device, and includes features for attachment to instrumentation for insertion, and the slots for the anchors.

The D-shaped ROI-C PEEK implants (PEEK OPTIMA LT1) feature two slots which allow for use with specially designed supplemental fixation – the ROI-C VerteBRIDGE anchoring plate. The anchoring plate, made of titanium alloy (TiAl6V4) can be inserted to obtain fixation to the vertebral bone and create a standalone cervical interbody fusion cage construct. The anchoring plate locks securely in place to the PEEK implant via locking tabs on either side of the anchoring plate.

The ROI-C PEEK cages are available in two shapes – an anatomic design with a curved superior surface and a lordotic design with flat superior and inferior surfaces to create 7° of lordosis. The device is manufactured from medical grade PEEK OPTIMA® LT1

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

Predicate Device:

The subject LDR Spine ROI-C Cervical Cage System is substantially equivalent to the primary predicate LDR Spine ROI-C Cervical Cage System (K113559) with respect to indications, design, function, and materials. An additional (secondary) predicate device was cited in the 510(k), which was the Amedica® Corporation Valeo™ Spacer System (K142264).

Substantial Equivalence:

The LDR Spine ROI-C Cervical Cage System and primary predicate LDR Spine ROI-C Cervical Cage System (K113559) are similar in design, materials, and indicated use, and are both cleared devices.

The LDR Spine ROI-C Cervical Cage System and additional (secondary) predicate Amedica® Corporation Valeo™ Spacer System (K142264) are similar in design, and indicated use, and are both cleared devices.

Performance Testing:

Comprehensive, clinical literature review data have been provided to investigate the risks and benefits associated with using allogenic bone graft with the LDR Spine ROI-C Cervical Cage System.

The published clinical outcomes demonstrated that the use of allograft (i.e., cancellous and/or corticocancellous bone graft) in cervical interbody fusion devices to treat patients diagnosed with cervical degenerative disc disease as defined above, poses no new risks to patients.

No new mechanical tests were performed since there were no design changes to the device.

Conclusion:

The LDR Spine ROI-C Cervical Cage System has been modified to expand the indications to permit use with allograft. The 510(k) demonstrates substantial equivalence to predicate devices.