



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

LDR Spine USA
Mr. James Wilson
Regulatory Affairs Specialist
13785 Research Boulevard, Suite 200
Austin, Texas 78750

December 7, 2015

Re: K151934
Trade/Device Name: ROI-C Titanium-Coated Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: November 6, 2015
Received: November 9, 2015

Dear Mr. Wilson:

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 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)
K151934

K151934

Page 1 of 1

Device Name

ROI-C Titanium-Coated Implant System

Indications for Use (Describe)

The LDR Spine ROI-C Titanium-Coated Implant 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 nonoperative treatment. The ROI-C Implant System implants are to be used with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft and implanted 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

K151934
Page 1 of 3

Owner's Name & Address:

LDR Spine USA
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Austin, TX 78750

Contact Person:

Mr. Jamie E. Wilson
Regulatory Affairs Specialist
Phone: (512) 344-3355
Fax: (512) 795-8306
Email: jamie.wilson@ldrspine.com

Date:

December 3, 2015

Trade Name:

LDR Spine Cervical Interbody Fusion System –
ROI-C Titanium-Coated Implant System

Common Name:

Intervertebral body fusion device with integrated fixation,
cervical

Panel:

Orthopedic

Product Code:

OVE

Classification:

Class II, 21 CFR 888.3080

Predicate Devices:

Primary Predicate:

LDR Spine Cervical Interbody Fusion System –
ROI-C Lordotic Implants (K113559)

Additional Predicates:

X-Spine Irix-C Spinal Implant System (K131951)
Centinel Spine Stalif-C® Ti (K133200)

Device Description:

The ROI-C Titanium-Coated Implant System consists of 'D' shaped blocks in two profiles, anatomic and lordotic, a variety of footprints within each profile, and features an enclosed graft space. Lateral rows of teeth are present on both the caudal and cephalic surfaces of the device. The flat portion of the 'D' shape represents the anterior most portion of the device and includes features for attachment to instrumentation for insertion and slots for VerteBRIDGE® integrated fixation anchoring plates. The D-shaped ROI-C

PEEK implants (PEEK OPTIMA LT1) are coated with plasma-sprayed commercially pure titanium on the inferior and superior surfaces and feature two slots which allow for use with specially designed (and optional) supplemental fixation described below. The ROI-C Titanium-Coated Implant also features a tantalum radiographic marker on the posterior edge of the device. The VerteBRIDGE Anchoring Plates are made of titanium alloy (TiAl6V4) and can be inserted to obtain fixation to the vertebral bone and create a standalone cervical interbody fusion cage construct. The VerteBRIDGE Anchoring Plate used with ROI-C is curved, allowing it to be inserted into the ROI-C device in-line with the cage and then seated into the superior and inferior vertebral endplates.

The ROI-C VerteBRIDGE Anchoring Plates are provided in two sizes: an 8mm length plate (intended for use with ROI-C devices height 4.5mm – 7mm) and a 9.5mm length plate (intended for use with ROI-C devices height 8mm –10mm). The anchoring plate locks into the ROI-C cage and provides stability to the construct via incorporated anti-back out tabs and a central retaining ridge.

Indications for Use:

The LDR Spine ROI-C Titanium-Coated Implant 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 nonoperative treatment. The ROI-C Implant System implants are to be used with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft and implanted via an open, anterior approach. Supplemental internal fixation is required to properly utilize this system.

Purpose of this submission:

The purpose of this submission is to extend the line of currently available ROI-C cages to include cages that incorporate a titanium coating. This introduction of the ROI-C Titanium-Coated Implant System is not a response to any design deficiency or complaint.

Non-Clinical Performance Data:

Non-clinical performance bench testing conducted to support substantial equivalence for the ROI-C Titanium-Coated Implant System 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 and engineering analysis

- Static cage expulsion testing
- Static anchoring plate expulsion testing
- Wear testing & debris analysis
- Coating characterization
- MRI compatibility testing

The results of this non-clinical testing demonstrate that the strength and performance of the ROI-C Titanium-Coated Implant System are sufficient for its intended use and the device 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 ROI-C Titanium-Coated Implant System is substantially equivalent to the predicate devices based on intended use and indications for use. The differences in technological characteristics between the subject and predicate devices 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 ROI-C Titanium-Coated Implant System overall is substantially equivalent to the predicate devices.