K110327

510(k) Summary of Safety and Effectiveness
LDR Spine ROI-A® Implant System

SEP 3 0 2011

Owner's Name & Address:

LDR Spine USA
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Contact Person:

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Date 510(k) Summary Prepared: September 29, 2011

Trade Name: LDR Spine ROI-A® Implant System

Common Name: Intervertebral Body Fusion Device (MAX)

Classification: MAX 888.3080 – Intervertebral Fusion Device with Bone Graft, Lumbar

Legally Marketed Predicate Device: LDR Spine ROI Implant System (K082262, K090507)

Device Description

The ROI- A Oblique implant 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 extremities to facilitate visibility in x-ray imaging. The subject device is designed for placement using an anterolateral approach with an approximate offset angle of 25° from the straight anterior axis.

Indications for Use:

When used as an intervertebral body fusion device, the *ROI-A 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 to facilitate fusion.

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Non-Clinical Performance Data: Testing was comprised of static shear compression, dynamic axial compression and dynamic bending (per ASTM F2077), expulsion (per ASTM F-04.25.02.02), wear debris analysis (per ASTM F1877), low cycle cadaver testing to evaluate clinical stability and device expulsion/pull-out, and high cycle cadaver testing to evaluate device loosening or migration, blade back-out and vertebral body damage. The results of this testing demonstrate that the performance of the LDR Spine ROI-A Oblique implant, when compared with its legally marketed predicate, is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LDR Spine USA
% Ms. Maritza Elias
Regulatory Affairs Project Manager
4030 West Braker Lane, Suite 360
Austin, Texas 78759

SEP 30 2011

Re: K110327
Trade/Device Name: LDR ROI-A Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: OVD
Dated: August 31, 2011
Received: September 1, 2011

Dear Ms. Elias:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110327

INDICATIONS FOR USE

510(k) Number (if known): K110327

Device Name: LDR Spine USA ROI-A® Implant System

Indications for Use:
When used as an intervertebral body fusion device, the ROI-A 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 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)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110327