K043349

JUN 2 9 2005

510(k) Summary *Premarket Notification, Section 510(k)*	*LDR Spine USA* JUNE 9, 2005

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. *Device Name:*

Trade Name: **Radiotransparent Open Implant *(ROI) – Partial Vertebral Body Replacement (PVBR)***

Common Name(s): Vertebral body replacement

Classification Name(s): Vertebral body replacement (MQP)

2. *Establishment Name & Registration Number:*

Name: ***LDR Spine USA***
Number: 3004903783

3. *Classification(s):*

21 CFR § Sec. 888.3060 Spinal intervertebral body fixation orthosis.

(a) ***Identification.*** A spinal intervertebral body fixation orthosis is a device intended to be implanted made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is used to apply force to a series of vertebrae to correct "sway back," scoliosis (lateral curvature of the spine), or other conditions.

Device Class: Class II for the requested indications
Classification Panel: Orthopaedic and Rehabilitation Devices Panel
Product Code(s): MQP

4. *Equivalent Predicate Device:*

LDR Spine USA proposes that the ***ROI*** is substantially equivalent to the following:

- EBI CAS Spine Spacer System– K042268
- Signus PEEK Tetris™ Spinal Implant – K031757
- Signus Curved PEEK Tetris™ Spinal Implant – K041888

Equivalence is demonstrated in the design, material composition, surgical technique and intended use.

5. *Device Description:*

The ROI vertebral implants consists of a series of flat and wedge shaped implants. The device is used singly or in pairs. The device is offered in nine different configurations to better approximate the anatomical variation observed in different vertebral levels and/or patient anatomy.

The LDR Spine USA, ROI Partial Vertebral Body Replacement System is comprised of a variety of components fabricated and manufactured from Polyetheretherketone (PEEK) as described by ASTM F-2026. This material is utilized due to its radiolucent properties, which aid the surgeon in determining if fusion in the operative site has occurred.

The LDR Spine ROI Partial Vertebral Body Replacement System is a two piece, hollow chamber, rectangular block. The superior and inferior surfaces of the construct have a pattern of teeth to provide increased stability and to help prevent movement of the device. Tantalum wire markers (ASTM F-560) are inserted into components to give surgeons a visual aid in determining the location of the implant, both inter and post-operatively. The device comes in various sizes and is offered in both straight and tapered styles.

Materials: all implants are made from implant grade PolyEtherEther-Ketone polymer (PEEK) with tantalum alloy position markers as indicated in the table below:

PEEK Optima LT	USP Class VI ASTM F-2026	ISO 10993
Tantalum	ASTM F-560	ISO 5832-3

Indications for Use. The ROI 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 internal fixation. The ROI may be implanted singularly or in pairs. Supplemental internal fixation is required to properly utilize this system.

Testing Summary. Fatigue and static testing is complete. Samples were tested according to accepted engineering and scientific principals. Test results demonstrate that the system can be expected to perform in a manner equivalent to the predicate devices.

6. ***Applicant Name & Address:***

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Office: (512) 344-3333
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7. ***Company Contact:***

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Dir. Reg. & Clinical Affairs
LDR Spine USA
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Austin, TX. 78759
Office: (512) 344-3316
Fax: (512) 344-3350

8. ***Submission Correspondent:***

Mr. Brian Burkinshaw
Dir. Innovation & Technology
LDR Spine USA
4030 W. Braker Ln., Ste. 360
Austin, TX. 78759
Office: (512) 344-3304
Fax: (512) 344-3350

9. ***Performance Standards:***

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, LDR Spine, USA Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 13485 series quality regulations.

LDR Spine USA also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

10. Storage, Packaging & Sterilization Information:

The implantable portions of the ***ROI*** are supplied ***"STERILE"***. The sterilization process is radiation and the selected protocol has been validated. The minimum Sterility Assurance Level (SAL) of at least 10^{-6}.

The instruments are supplied non-sterile and must be cleaned and sterilized prior to first use and each subsequent use. The recommended sterilization process for the instruments is high temperature steam autoclave sterilization. The referenced sterilization cycle produces a Sterility Assurance Level (SAL) of at least 10^{-6}.

The validated cycle is:
Method: Steam
Cycle: Gravity
Temperature: 270°F (134°C)
Exposure Time: 18 minutes

All packages containing implants or instruments should be intact upon receipt. Damaged packaging may indicate the presence of unsafe product. If the package or product is damaged, the product should not be used and should be returned. Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination. When used, the product must be placed into use following cleaning, sterilization and accepted surgical sterile technique.

11. Summary Comparison Table:

FEATURE	*ROI*	*CAS Spine Spacer System*	*PEEK and Curved PEEK Tetris™ Spinal Implant*	*SE?*
Indications for Use:	The ROI 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 thoraco-lumbar spine (from TI to L5) and is intended for use with supplemental internal fixation. The ROI may be implanted sinularly or in pairs. Supplemental fixation is required to properly utilize this system	Same as ROI	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 vertebral body replacement in the thoracolumbar spine (from TI to L5) and is intended for use with supplemental internal fixation.	YES
Design:	Modular Cage	Cage	Same as CAS SSS	YES
Supplied Sterile:	Yes – Gamma radiation	Yes	Yes – Gamma radiation	YES
Material:	PEEK w/ tantalum markers	Titanium	PEEK w/ titanium markers	YES
Instruments:	Specialized reusable instruments are required. Instruments must be cleaned and sterilized prior to 1st use and each subsequent use.	Same	Same	YES
How used:	Singularly or in pairs	Same	Singularly	YES
K Number:	K043349 (under review)	K042268	K031757 - K041888	YES
Manufacturer:	LDR Medical	EBI	Signus Medizintechnik, Gmbh	YES
Product Code:	MQP	MQP	MQP	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2005

Mr. Brian Burkinshaw
Director, Innovation and Technology Solutions
LDR Spine USA Incorporated
4030 West Braker Lane, Suite 360
Austin, Texas 78759

Re: K043349
Trade/Device Name: Radiotransparent Open Implant (ROI)- Partial Vertebral Body Replacement (PVBR)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: June 9, 2005
Received: June 10, 2005

Dear Mr. Burkinshaw:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043349

510(k) Number: K043349

Device Name(s): *Radiotransparent Open Implant (ROI) – Partial Vertebral Body Replacement (PVBR)*

Indications for Use:

The ROI 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 TI to L5) and is intended for use with supplemental internal fixation. The ROI may be implanted singularly or in pairs. Supplemental internal fixation is required to properly utilize this system.

Prescription Use ____X____ OR Over-The-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043349

(Per 21 CFR 801.109) (Optional format 1-2-96)