Special 510(k): Device Modification
510(k) Summary
Easyspine® System

Sponsor Name: LDR Spine USA
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JAN 2 4 2007

Official Contact: James Burrows

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Telephone (858) 792-1235
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DEVICE NAME

Classification Name: Orthosis, Spinal Pedicle Fixation (MNI)
Orthosis, Spondylolisthesis Spinal Fixation (MNH)

Trade/Proprietary Name: Easyspine® System

Common Name: Pedicle Screw Spinal System

ESTABLISHMENT REGISTRATION NUMBER
LDR Spine USA has submitted an Establishment Registration to FDA. The Establishment Registration number is 3004903783. The Owner/Operator number is 9068076.

DEVICE CLASSIFICATION
The Easyspine system is a Class II pedicle screw spinal system (21 CFR 888.3070). The product code for Orthosis, Spondylolisthesis Spinal Fixation is MNH. The product code for Orthosis, Spinal Pedicle Fixation is MNI. These device classifications are reviewed by the Orthopedic Devices Branch.

PREDICATE DEVICE INFORMATION
The predicate device for this modification is the Easyspine System cleared by FDA under K043094 and K061017.

LABELING
Package labels are similar in format and content to previously cleared labels for the unmodified Easyspine System. The system modifications described in this submission do not necessitate changes to the Package Insert.

PACKAGING AND STERILIZATION
Packaging and sterilization will not change with the modifications described in this submission.

INTENDED USE
The Easyspine System is a posterior, noncervical, pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: spondylolisthesis (grades 3 and 4 at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment), trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

DEVICE DESCRIPTION
Modifications to the Easyspine System that are the subject of this submission are confined solely to the addition of 5 mm diameter screws, 8 mm diameter screws, and washers (also referred to as spacers.) No components of the predicate (unmodified) system have been modified or deleted.

Material Composition and Biocompatibility
The rods, pedicle screws and components, set screws, connectors and washers of the Easyspine System are made of titanium alloy conforming to the requirements of ASTM F 136, *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*. The titanium material is biocompatible, corrosion-resistant, and not toxic in a biologic environment allowing for artifact-free x-ray imaging, computed tomography (CT) and Magnetic Resonance Imaging (MRI).

EQUIVALENCE TO MARKETED PRODUCT

The modified Easyspine System has the following similarities to the predicate Easyspine System:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials, and
- is packaged and sterilized using the same materials and processes.

In summary, the modified Easyspine System described in this submission is, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

LDR Spine USA
% Mr. Floyd G. Larson
President
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

JAN 24 2007

Re: K063794
Trade/Device Name: Easyspine® System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: December 21, 2006
Received: December 22, 2007

Dear Mr. Larson:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

Applicant: LDR Spine USA

510(k) Number (if known): _____

Device Name: Easyspine System

Indications for Use:

The LDR Easyspine System is a posterior, noncervical, pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: spondylolisthesis (grades 3 and 4 at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment), trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 General, Restorative, and Neurological Devices

510(k) Number K063794