K102331

510(k) Summary

OCT 15 2010

LDR Spine SpineTune™ TL Spinal System
Addition of Cannulated Pedicle Screws and Additional Size Rods

1. **Owner's Name & Address**

LDR Spine USA
4030 West Braker Lane, Suite 360
Austin, TX 78759

Phone: (512) 344-3333
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2. **Contact Person**

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Quality Engineering and Regulatory Affairs Project Manager
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3. **Date 510(k) Summary Prepared:** September 16, 2010

4. **Trade Name:** LDR Spine SpineTune™ Spinal System
Common Name: Spinal Fixation System (MNH, MNI, KWP)
Classification: MNH 888.3070 – Orthosis, Spondilolisthesis Spinal Fixation
MNI 888.3070 – Orthosis, Spinal Pedicle Fixation
KWP 888.3050 – Orthosis, Spinal Interlaminal Fixation

5. **Legally Marketed Equivalent Predicate Device:**
SpineTune™ Spinal System (K100575)
OPTIMA™ Spinal System (K024096)

6. **Device Description**
The SpineTune™ TL Spinal System is a top-loading multiple fixation system which consists of pedicle screws, straight rods, curved cods, connectors and set screws. The cannulated polyaxial pedicle screw design and additional sizes of the straight and curved rods are an addition to the previously cleared SpineTune™ TL Spinal System (K100575).

7. **Intended Use of the Device**
   The SpineTune™ TL Spinal System is a posterior, noncervical pedicle fixation system indicated to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion by autogenous bone graft in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine:
   - Spondylolisthesis (Grade 3 and 4)
   - Degenerative spondylolisthesis with objective evidence of neurological impairment
   - Trauma (i.e., fracture or dislocation)
   - Spinal stenosis
   - Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
   - Tumor
   - Pseudoarthrosis
   - Failed previous fusion

8. **Non-Clinical Performance Data**
   The outcomes of non-clinical testing performed (static compression bending, static torsion, and axial compression fatigue testing) according to ASTM 1717 indicate that the cannulated polyaxial screw addition to the SpineTune™ Spinal System is substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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OCT 15 2010

Re: K102331
Trade/Device Name: SpineTune™ TL Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWP
Dated: September 17, 2010
Received: September 20, 2010

Dear Ms. Nowatzke:

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,

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

Enclosure

K102331

OCT 15 2010

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: LDR Spine USA SpineTune™ TL Spinal System

Indications for Use:

The SpineTune™ TL Spinal System is a posterior, noncervical pedicle fixation system indicated to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion by autogenous bone graft in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine:

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- Tumor
- Pseudoarthrosis
- Failed previous fusion

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (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

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