

510(k) Summary
LDR Spine USA SpineTune TL Spinal System

JUN 27 2012

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Regulatory Affairs Specialist

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Austin, TX 78750
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Date: March 9, 2012

Common Name: Pedicle Screw Spinal System

Classification Name: Pedicle Screw Spinal System (per CFR 888.3070)

Product Codes: MNH (per CFR 888.3070)- Orthosis, Spondilolisthesis
Spinal Fixation
MNI (per CFR 888.3070)- Orthosis, Spinal Pedicle
Fixation
KWP (per CFR 888.3050)- Orthosis, Spinal
Interlaminar Fixation

Proprietary Name: LDR Spine SpineTune TL Spinal System

Legally Marketed Predicate Device: LDR Spine SpineTune TL Spinal System
(K100575, K102331)

Device Description The SpineTune TL Spinal System is a top-loading posterior spinal pedicle fixation system consisting of various pedicle screws, rods, set screws, and transverse, lateral, axial, and domino type connectors. The 8.0mm and 8.5mm polyaxial screws are a design modification of the 8.0mm and 8.5m polyaxial screws

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cleared in the predicate SpineTune TL Spinal System (K100575, K102331). Cannulated 8.0mm and 8.5mm polyaxial screws, additional lengths of 7.5mm polyaxial, monoaxial, and reduction screws and curved rods, and several device specific instruments, are additions to the previously cleared 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:

- 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

Non-Clinical

Non-clinical testing on the proposed 8.0mm and 8.5mm diameter polyaxial screws included an engineering analysis and the following mechanical tests:

- Dynamic Compression Bending Test (ASTM F-1717)
- Flexion-Extension Cantilever Test (ASTM F-1798)
- Axial Gripping Capacity Test (ASTM F-1798)
- Overtightening Test (ASTM F-1798)
- Static Torsion Test (ASTM F-1717)

The results of these tests were compared to the predicate SpineTune TL Spinal System in order to

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verify that the proposed screws meet the acceptance criteria set forth by the predicate screws.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe and effective, and performs as well or better than the legally marketed predicate device. Therefore, the data demonstrates that the subject device is substantially equivalent to the predicate device.



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

JUN 27 2012

LDR Spine USA, Inc.
% Ms. Kiersten Soderman
Regulatory Affairs Specialist
13785 Research Boulevard, Suite 200
Austin, Texas 78750

Re: K120760
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: MNH, MNI, KWP
Dated: May 29, 2012
Received: May 30, 2012

Dear Ms. Soderman:

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.

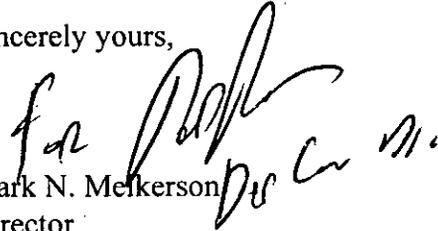
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/ucml15809.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" (21 CFR 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. Melkersen
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: LDR Spine SpineTune™ TL Spinal System

Indications for Use:

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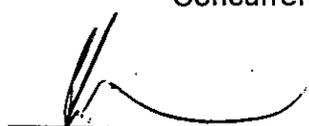
Prescription Use X
(Part 21 CFR 801 Subpart D)

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

510(k) Number K120760