510(k) Summary

SEP 29 2010

LDR Spine C-Plate™ Anterior Cervical Plate System

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

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

Phone: (512) 344-3333
Fax: (512) 344-3350

2. **Contact Person**

Beckinam Nowatzke, MSRS
Quality Engineering and Regulatory Affairs Project Manager
LDR Spine USA
4030 West Braker Lane, Suite 360
Austin, TX 78759

Phone: (512) 344-3407
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Email: beckinowatzke@ldrspine.com

3. **Date 510(k) Summary Prepared:** September 2, 2010

4. **Trade Name:** LDR Spine C-Plate™ Anterior Cervical Plate System
Common Name: Anterior Cervical Plate System (KWQ)
Classification: KWQ (per 21 CFR 888.3060) – Spinal intervertebral body fixation orthosis

5. **Legally Marketed Equivalent Predicate Device:**
MAXIMA™ Anterior Cervical Plate System (K061002)

6. **Device Description**
The C-Plate Anterior Cervical Plate System consists of a variety of shapes and sizes of Main Plates, screw, sub-plate, rivets and associated instruments.

7. **Intended Use of the Device**
The C-Plate™ Anterior Cervical Plate System is intended for anterior cervical fixation for the following indications:

- degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- spondylolisthesis,

- trauma (i.e., fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- tumor,
- pseudoarthrosis,
- failed previous fusion.

A section outlining the technological characteristics and specific performance tests is not applicable for this submission.

The proposed LDR Spine C-Plate™ Anterior Cervical Plate System is exactly the same as the predicate MAXIMA™ Anterior Cervical Plate System (cleared via K061002) and the purpose of this submission is to transfer the ownership and name of the device.

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

SEP 29 2010

LDR Spine USA
% Beckinam Nowatzke, MSRS
Quality Engineering and Regulatory Affairs Project Manager
4030 West Braker Lane, Suite 360
Austin, Texas 78759

Re: K102265
Trade/Device Name: C-Plate™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 02, 2010
Received: September 03, 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

K102265

SEP 29 2010

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: LDR Spine USA C-Plate™ Anterior Cervical Plate System

Indications for Use:

The C-Plate™ Anterior Cervical Plate System is intended for anterior cervical fixation for the following indications:

- Degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- 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

510(k) Number K102265