K083077

5. 510(k) Summary

[As Required by 21 CFR 807.87(h) & 21 CFR 807.92]

OCT 2 6 2009

1. Submission information

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Date Prepared: 30 Sep, 2008

2. Device Identification

Trade Name: ULC spinal pedicle screw system
Common Name: Pedicle Screw Spinal Fixation system
Classification: Class Ⅱ
MNI 888.3070 – Orthosis, Spinal Pedicle Fixation.
MNH 888.3070 – Orthosis, Spondyloisthesis Spinal Fixation.

3. Substantial Equivalence Predicate Legally Marketed Devices

BK Meditech Co., Ltd., MEGA spine system – MNI MNH – K072436
Jemo Spine, LLC., DELTA™ spinal fusion system – MNI MNH KWQ – K071857
Stryker Spine, Xia® Spinal system – MNI MNH KWP KWQ – K053115

U&I Corporation, OPTIMA™ Spinal System – MNI MNH KWQ – K051971

The substantial equivalence of this device is based on equivalence in intended use, materials, designs and operational principles to the above listed predicate devices.

4. Device Description

The ULC spinal pedicle screw system is one touch single unitary locking cap, posterior spinal fixation system which consists of pedicle screws (mono-axial screw & poly-axial screw), rod and locking cap.

The ULC system will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. Components of the ULC system are supplied non-sterile and single use.

The ULC system is fabricated from titanium alloy (Ti-6AI-4V ELI) that conforms to ASTM F 136. Various sizes of these implants are available. Specialized instruments made from surgical grade stainless steel are available for the application and removal of the ULC Spinal pedicle screw systems.

5. Indications for Use

The ULC spinal pedicle screw systems are intended for posterior and non-cervical pedicle fixation for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the ULC is 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: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

6. Statement of Technological Comparison

Bench testing as listed in **Section 14** and **Appendix D**. was conducted in accordance with ASTM F1717. It demonstrates substantial equivalence to the above listed predicate devices in terms of materials, design, indications for use and operational principles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Otis Biotech Co., LTD
% Jisuk Yoo
514, 2-BA Block, Jungwang-Dong, Sihma
Sihung City, Kyonggi-do
Republic of Korea 429-450

OCT 2 3 2009

Re: K083077
Trade/Device Name: ULC Spinal Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: October 21, 2009
Received: October 21, 2009

Dear Mr. Yoo:

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 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 (240) 276-3150 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

4. Indications for Use

510(k) Number: k083077

Device Name: **ULC spinal pedicle screws system**

Indications For Use:

The ULC spinal pedicle screw systems are intended for posterior and non-cervical pedicle fixation for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083077