K071880

U&I CORPORATION

510(k) Summary

OCT 5 " 2007

Manufacturer:
U & I Corporation
529-1, Yonghyun-dong, Uijungbu
Kyonggi-Do, Korea 480-050
Dae-Kyoon, Rah, Regulatory Affairs Manager

Sponsor:
Zimmer Spine, Inc.
7375 Bush Lake Road
Minneapolis, MN 55439

Sponsor Contact:
Nicole Bowden
Regulatory Affairs Associate

Date Prepared:
July 2, 2007

Device Name:
Trade Name: *OPTIMA™* ZS Transition Screw

Common Name:
Spinal Fixation System

Classification Name:
Orthosis, Spondylolisthesis Spinal Fixation (MNH), per 21 CFR 888.3070

Orthosis, Spinal Pedicle Fixation (MNI), per 21 CFR 888.3070

Spinal Interlaminal Fixation Orthosis (KWP), per 21 CFR 888.3050

Product Code:
MNH, MNI and KWP

Predicate Devices:
OPTIMA™ ZS Spinal System

Description of Device:

The *OPTIMA™* ZS Transition Screw is a posterior pedicle screw that is used as a transition device when the Zimmer GmbH *Dynesys®* Spinal System and the *OPTIMA* ZS Spinal System are used on contiguous levels. The *OPTIMA* ZS Transition Screw interfaces with the rod section of the *Zimmer® DTO™* Implant, cord-rod combination implant. The cord portion of the *Zimmer® DTO™* Implant interfaces with the *Dynesys* Spinal System.

Intended Use:

The *OPTIMA*™ ZS Spinal System is a posterior pedicle screw fixation system indicated 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 with removal of implants after the attainment of a solid fusion.

In addition, The *OPTIMA*™ ZS Spinal System 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 of the vertebral body
- Dislocation
- Scoliosis
- Kyphosis
- Spinal tumor
- Failed previous fusion (pseudoarthrosis).

When the Zimmer GmbH *Dynesys*® Spinal System and the *OPTIMA*™ ZS Spinal System are used on contiguous levels, they must be used with the Zimmer GmbH *Zimmer*® *DTO*™ Implant, rod-cord combination implant, and the *OPTIMA*™ ZS Transition Screw. The indications for use for each level is as specified for each system.

Substantial Equivalence:

The *OPTIMA* ZS Transition Screw is substantially equivalent to the pedicle screws of the *OPTIMA* ZS Spinal System in design, materials, function and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

U & I Corporation
% Zimmer Spine, Inc.
Ms. Nicole Bowden
Regulatory Affairs Associate
7375 Bush Lake Road
Minneapolis, MN 55441

OCT 5 ˜ 2007

Re: K071880
Trade/Device Name: OPTIMA™ ZS Transition Screw
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH, KWP
Dated: July 2, 2007
Received: July 9, 2007

Dear Ms. Bowden:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for the indication of spinal stabilization without fusion have not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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); 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 information about the application of other labeling requirements to your device (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" (21 CFR 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: OPTIMA™ ZS Transition Screw

Indications for Use:

The *OPTIMA™* ZS Spinal System is a posterior pedicle screw fixation system indicated 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 with removal of implants after the attainment of a solid fusion.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071880