510(k) SUMMARY
Zimmer® Dynesys® Top-Loading Spinal System

510(k) Number K092234

OCT 21 2009

Date of Summary Preparation: July 22, 2009

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

Company Contact:
Elsa A. Linke
Regulatory Affairs

Manufacturer:
Zimmer GmbH
Sulzerallee 8
CH-8404 Winterthur
Switzerland

Device Name: Dynesys® Top-Loading Spinal System

Common Name: Spinal Fixation System

Classification Name: Posterior Metal/Polymer Spinal System, Fusion

Product Code: NQP

Regulation Number: 21 CFR 888.3070

Device Classification: Class II

Predicate Devices:
Dynesys® Top-Loading Spinal System
Zimmer Spine ST360°® Spinal System
TiTLE® 2 Polyaxial Screw System

Description of Device:
The Zimmer® Dynesys® Spinal System, including the *Dynesys* Top-Loading Spinal System, is a temporary implant system used to correct spinal deformity and facilitate the biological process of spinal fusion. This system is intended for non-cervical posterior use in the lumbar and sacral areas of the spine. Implants of this system consist of fixed pedicle screws of varying diameters and lengths, set screws, polycarbonate urethane (PCU) spacers, and polyethylene terephthalate (PET) cords.

The *Dynesys* pedicle screw consists of a top-loading solid or cannulated shank, either uncoated or coated with ceramic hydroxyapatite (HA). The *Dynesys* Spinal System is also cleared for connection with the *Zimmer DTO* implant. The *Zimmer DTO* implant allows the connection of the *Dynesys* Spinal System to the *Optima* ZS Spinal System when the two systems are used on contiguous levels.

Intended Use:

When used as a pedicle screw fixation system in skeletally mature patients, the *Dynesys* Spinal System is intended to provide immobilization and stabilization of spinal segments 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 neurologic impairment, and failed previous fusion (pseudoarthrosis).

In addition, when used as a pedicle screw fixation system, the *Dynesys* Spinal System is indicated for use in patients:

- Who are receiving fusions with autogenous graft only;
- Who are having the device fixed or attached to the lumbar or sacral spine;
- Who are having the device removed after the development of a solid fusion mass.

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

Comparison of Technological Characteristics:

The *Dynesys* Top-Loading Spinal System shares the same technological characteristics as the predicate devices. These characteristics include similar design, materials, range of sizes, technical requirements, and intended use.

Substantial Equivalence:

The *Dynesys* Top-Loading Spinal System is substantially equivalent to the predicate devices in design, materials, function and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Zimmer Spine
% Ms. Elsa A. Linke
Senior Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439-2027

OCT 21 2009

Re: K092234
Trade/Device Name: Dynesys® Top-Loading Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: II
Product Code: NQP
Dated: July 22, 2009
Received: July 23, 2009

Dear Ms. Linke:

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 Warning section of the device's labeling:

> *"The safety and effectiveness of this device has not been established for the intended use of spinal stabilization without fusion. This device is only intended to be used when fusion with bone graft is being performed at all instrumented levels."*

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); 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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/cdrh/industry/support/index.html.

Sincerely yours,

Christy Foreman for

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K092234

Device Name: **Dynesys® Top-Loading Spinal System**

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Prescription Use X (Part 21 CFR 801 Subpart D) 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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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