K043565

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MAR 1 1 2005

510(k) SUMMARY

Submitter:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, MN 55439
Company Contact:	Tim Crabtree Senior Regulatory Affairs Specialist
Date Prepared:	December 15, 2004
Device Name:	Trade Name: Dynesys® Spinal System Common Name: Spinal Fixation System.
Classification Name:	Posterior Metal/Polymer Spinal System, Fusion
Predicate Devices:	Dynesys® Spinal System (K031511)

Description of Device: The Dynesys Spinal System is comprised of a variety pedicle screws sizes, tensioning cords and longitudinal spacers that are uniquely fitted for each individual case. The pedicle screws are manufactured from medical grade titanium alloy. The tensioning cords are manufactured from Sulene-PET (polyethylene-terephthalate). The longitudinal spacers are manufactured from Sulene-PCU (polycarbonate-urethane).

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.

Comparison of Technological Characteristics:

Testing and analysis of proposed additional screw components for the Dynesys Spinal System was performed. The results of this testing demonstrated that the there are no technological differences between the proposed screw sizes and the components in the current Dynesys Spinal System.

Substantial Equivalence:

The additional components of the Dynesys Spinal System are substantially equivalent to the original Dynesys Spinal System components based on materials, design, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tim Crabtree
Senior Regulatory Affairs Specialist
Zimmer Spine
7375 Bush Lake Road
Minneapolis, Minnesota 55439

MAR 1 1 2005

Re: K043565
Trade/Device Name: Dynesys Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: NQP
Dated: February 10, 2005
Received: February 11, 2005

Dear Mr. Crabtree:

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.

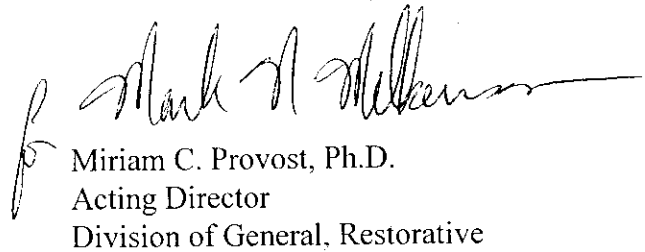
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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

If you desire specific advice for your device on our labeling regulation (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" (21CFR 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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number : ~~Pending~~ K043565

Device Name: Dynesys® Spinal System

Indications for 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 (pseudarthrosis).

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Mark N Milleman

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

510(k) Number K043565

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)