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K042702
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510(k) SUMMARY

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

Company Contact: Tim Crabtree
Senior Regulatory Affairs Specialist

Date Prepared: November 19, 2004

Device Name: Trade Name: Silhouette™ Spinal Fixation System

Common Name: Spinal Fixation System.

Classification Name: Spinal interlaminal fixation orthosis
Pedicle screw spinal system

Predicate Devices: Silhouette™ Spinal Fixation System (K980288)

Description of Device:

The Zimmer Spine Silhouette Spinal Fixation System is a temporary implant system used to correct spinal deformity and facilitate the biological process of spinal fusion. This system is intended for the noncervical posterior use in the thoracic, lumbar and sacral areas of the spine. Implants of this system consist of hooks and/or screws connected to rods and are intended to be removed after solid fusion has occurred. The system includes polyaxial screws of varying diameters and lengths, fixed screws of varying diameters and lengths, rods in varying lengths, hooks in varying designs, fixed and adjustable transverse connectors. All implant components are top loading and top tightening. All the implants in this system are manufactured from titanium alloy (Ti-6A1-4V) conforming to ASTM F-136.

Intended Use:

The Silhouette™ Spinal System is intended for posterior, noncervical pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture and dislocation); spinal stenosis; deformities (i.e. scoliosis, kyphosis and/or

lordosis); tumor; pseudoarthrosis; and failed previous fusion. Pedicle screw fixation is limited to skeletally mature patients.

When used as a hook and sacral screw system, the Silhouette Spinal Fixation System is intended for use in the treatment of degenerative disc disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal fusion. When used for this indication, screws of the Silhouette™ Spinal Fixation System are intended for sacral iliac attachment only. Hook and transverse connectors of the system are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use for the hook and sacral screw fixation of this system are T1 to the sacrum.

Comparison of Technological Characteristics:

There are no technological differences between the Silhouette Spinal Fixation System and the previously cleared Silhouette Spinal Fixation System.

Substantial Equivalence:

The Silhouette Spinal System is substantially equivalent to the original Silhouette Spinal System based on materials, design, function and the supporting information included in the Class III Certification and Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 3 2004

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

Re: K042702
Trade/Device Name: Silhouette™ Spinal Fixation System
Regulation Number: 21 CFR 888.3050, 888.3070
Regulation Name: Spinal interlaminal fixation orthosis; pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, KWP, MNH, MNI
Dated: September 29, 2004
Received: September 30, 2004

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.

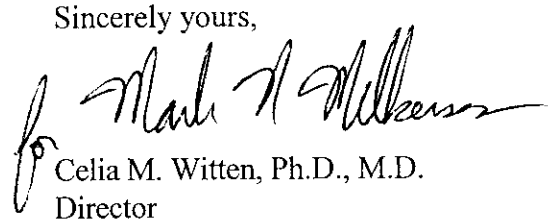
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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-. 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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
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 : K042702

Device Name: Silhouette™ Spinal Fixation System

Indications for Use: The Silhouette™ Spinal System is intended for posterior, noncervical pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture and dislocation); spinal stenosis; deformities (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. Pedicle screw fixation is limited to skeletally mature patients.

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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)

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

510(k) Number K042702