K040493

ADMINISTRATIVE INFORMATION

SEP - 3 2004

Manufacturer Name: Orthopedic Sciences, Inc.
6080 Center Drive, 6th Floor
Los Angeles, CA 90045

Official Contact: James K. Brannon, M.D.
President/CEO
Telephone (310) 242-6643
FAX (310) 242-6603

Representative/Consultant: Floyd G. Larson
PaxMed International
4329 Graydon Road
San Diego, CA 92130
Telephone (858) 792-1235
FAX (858) 792-1236

DEVICE NAME

Classification Name: Pedicle Screw System (MNI [Class II uses]) per 21 CFR Part 888.3070

Spondylolisthesis Spinal Fixation Device (MNH) Per 21 CFR Part 888.3070

Trade/Proprietary Name: Outologous™ Spinal Fixation System

Common Name: Pedicle Screw Fixation System

DEVICE CLASSIFICATION

Pedicle screw fixation systems are assigned to Class II by FDA. The product codes for the Outologous Spinal Fixation System are MNI (Class II uses) and MNH.

INTENDED USE

The Outologous Spinal Fixation System is a pedicle screw fixation system indicated for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone grafting having implants attached to the lumbar and sacral spine with removal of implants after the attainment of a solid fusion.

In addition, the Outologous Spinal Fixation System is intended to provide immobilization and stabilization of the 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 spines: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture of the vertebral body, dislocation, scoliosis, kyphosis, spinal tumor, and failed fusions (pseudoarthrosis).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 2004

Orthopedic Sciences, Inc.
C/o Mr. Floyd G. Larson
PAXMED International
4329 Graydon Road
San Diego, California 92130

Re: K040493
Trade/Device Name: Outologous™ Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI
Dated: August 26, 2004
Received: August 27, 2004

Dear Mr. Larson:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for

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

510(k) Number: K040493

Device Name: Outologous™ Spinal Fixation System

Indications for Use:

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K040493