K053276

DEC 2 7 2005

I. 510(k) SUMMARY

November 23, 2005

SUBMITTER: Innovative Spinal Technologies
PO Box 110
Mansfield, MA 02048

CONTACT PERSON: Stephen Palumbo
Innovative Spinal Technologies
Telephone: 508/618-1295
Fax: 508/618-1296

TRADE NAME: IST Pedicle Screw System

FDA CLASSIFICATION/ CODE: 888. 3070; MNI, MNH, NKB

DEVICE DESCRIPTION: The IST Pedicle Screw System includes pedicle screws, polyaxial screw heads, locking caps and rods. The components are fabricated from titanium alloy (ASTM F-136). The system can be used in either percutaneous or open surgery procedures. The system components are provided clean and non-sterile for steam sterilization at the user's facility.

INTENDED USE: When used as a pedicle screw fixation system in the lumbar spine of skeletally mature patients, the IST Pedicle Screw System is intended for 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 lumbar spine: 1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies) 2) spinal stenosis, 3) spondylolisthesis, 4) fracture, 5) deformity, 6) spinal tumor and 7) failed previous fusion (pseudoarthrosis).

In addition, when used as a pedicle screw fixation system, the IST Pedicle Screw System is intended for skeletally mature patients: 1) having severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, 2) who are receiving fusion by autogenous bone graft only; 3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and 4) who are having the device removed after the development of a solid fusion mass.

PERFORMANCE DATA: Performance data were submitted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2005

Mr. Stephen Palumbo
Director, Quality & Regulatory Affairs
Innovative Spinal Technologies
PO Box 110
Mansfield, MA 02048

Re: K053276
Trade/Device Name: Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: November 23, 2005
Received: November 30, 2005

Dear Mr. Palumbo:

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,

for Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number: K053276

Device Name: IST Pedicle Screw System

Indications:

Open or percutaneous approach:

When used as a pedicle screw fixation system in the lumbar spine of skeletally mature patients, the IST Pedicle Screw System is intended for 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 lumbar spine: 1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies) 2) spinal stenosis, 3) spondylolisthesis, 4) fracture, 5) deformity, 6) spinal tumor and 7) failed previous fusion (pseudoarthrosis).

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Prescription Use ___X___ (21 CFR 801 Subpart D) or Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K053276