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JAN 2 2 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR:	Pioneer Surgical Technology 375 River Park Circle Marquette, Michigan 49855-1781 Contact: Jonathan Gilbert
DEVICE NAME:	Pioneer Posterior Cable Screw
CLASSIFICATION:	The classification of pedicle screw spinal system (§888.3070) and cerclage (§888.3010) is Class II, as per the Code of Federal Regulations, Title 21. The product codes are MNI and JDQ, respectively.
PREDICATE DEVICE:	The ParsFix Cable-Screw System (K003351 – SE 01/24/01, Spinal Concepts, Inc. – Austin, TX)
DEVICE DESCRIPTION:	Proprietary Name: Pioneer Posterior Cable Screw Common Name: Posterior Cable Screw
INTENDED USE:	The Posterior Cable Screw System is designed as an adjunct to any stainless steel, rigid, posterior fixation cleared/approved for trauma and sponylolithesis and is intended to reduce pars defect and to stabilize the spinal operative site during fusion procedures. A spinous process Grommet is included as part of the system. The system is designed as an adjunct to any stainless steel, rigid, posterior fixation and is indicated for the following: • Defect of the pars interarticularis • Spondylolithesis The Posterior Cable Screw System is indicated for pedicle screw attachment for these indications between T1 and the sacrum. Cables and spinous process Grommets may be used for interspinous wiring if additional stability is needed.
MATERIAL:	Implant grade stainless steel (ASTM F138 and ISO 5832-1.)
PERFORMANCE DATA:	Mechanical information was presented to support a determination of SE.
BASIS OF SUBSTANTIAL EQUIVALENCE:	The Pioneer Posterior Cable Screw system is similar to the components of a previously cleared device. The material is comprised of implant grade stainless steel. Supplemental fixation devices are intended for use with the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2004

Mr. Jonathan Gilbert
Director, Regulatory Affairs
Pioneer Surgical Technology
375 River Park Circle
Marquette, Michigan 49855-1781

Re: K022908
Trade/Device Name: Pioneer Posterior Cable Screw
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3010
Regulation Name: Pedicle screw spinal system, Bone fixation cerclage
Regulatory Class: II
Product Code: MNI, JDQ
Dated: November 28, 2003
Received: December 2, 2003

Dear Mr. Gilbert:

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) 594-4639. 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 Mark N. Melkerson

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

510(k) Number (if known): K022908

Device Name: Pioneer Posterior Cable Screw

INDICATIONS:

The Posterior Cable Screw System is designed as an adjunct to any stainless steel, rigid, posterior fixation cleared/approved for trauma and spondylolisthesis and is intended to reduce pars defect and to stabilize the spinal operative site during fusion procedures. A spinous process Grommet is included as part of the system. The system is designed as an adjunct to any stainless steel, rigid, posterior fixation and is indicated for the following:

- Defect of the pars interarticularis
- Spondylolithesis

The Posterior Cable Screw System is indicated for pedicle screw attachment for these indications between T1 and the sacrum.

Cables and spinous process Grommets may be used for interspinous wiring if additional stability is needed.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_
(Per 21 CFR 801.109)

for Mark N Milhous

Director

Division of General, Restorative and Neurological Devices

K022908