JUL 2 3 2004

3.0 Summary of Safety and Effectiveness Information

SPONSOR:	PIONEER SURGICAL TECHNOLOGY 375 River Park Circle Marquette, MI 49855 (906) 226-4812 Contact: Jonathan M. Gilbert
DEVICE NAME:	Quantum Spinal System
CLASSIFICATION NAME:	Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, Spondylolisthesis Spinal Fixation Device System and Pedicle Screw Spinal System, Class II.
INTENDED USE:	The Quantum Spinal System components are non-cervical spinal fixation devices intended for use as a posterior pedicle screw system (T1 - S2) or as an anterolateral fixation system (T8 – L5). Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthosis, and failed previous fusion.
Performance and SE Determination:	Comparisons of device performance data, materials, indications and design/function to predicate devices were provided in making a determination of substantial equivalence*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2004

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

Re: K041167
Trade Name: Pioneer Quantum Spinal System
Regulation Number: 21 CFR 888.3050, 888.3060, 888.3070
Regulation Name: Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, Pedicle Screw Spinal System
Regulatory Class: Class III
Product Code: NKB, KWP, MNH and MNI
Dated: April 30 and July 1, 2004
Received: May 4 and July 6, 2004

Dear Mr. Gilbert:

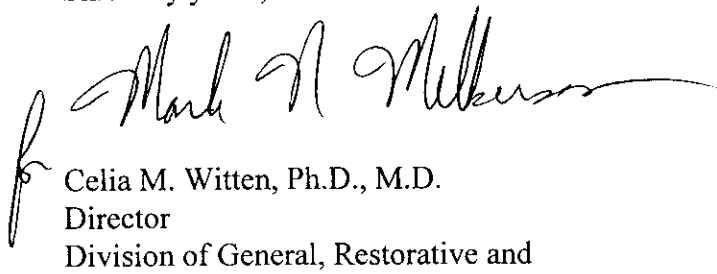
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 594-4659. 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,



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

2.0 Indications for Use Statement

Indications For Use Statement

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510(k) Number (if known): K041167

Device Name: Quantum Spinal System

Indications:

The Quantum Spinal System components are non-cervical spinal fixation devices intended for use as a posterior pedicle screw system (T1 - S2) or as an anterolateral fixation system (T8 – L5). Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthosis, and failed previous fusion.

(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 Milhorn

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

510(k) Number K041167