Pioneer Spine 510(k) Premarket Notification Vertebral Spacer

K061151

Page 1 of 1

SPONSOR:	PIONEER SURGICAL TECHNOLOGY 375 River Park Circle Marquette, MI 49855 Contact: Jonathan M. Gilbert (906) 226-4812

JUL 24 2006

DEVICE NAME:	Vertebral Spacer
CLASSIFICATION:	The classification of the Pioneer Vertebral Spacer is Class II, as per the Code of Federal Regulations, Title 21, Section 888.3060: Implant, fixation, spinal intervertebral body fixation orthosis devices. The product code is MQP. The Panel code is 87.
PREDICATE DEVICE:	K043206
DEVICE DESCRIPTION:	The Pioneer Vertebral Spacer is a radiolucent vertebral body replacement device of various heights and footprints used in conjunction with supplemental internal fixation to provide structural stability in skeletally mature individuals following partial replacement of a diseased vertebral body.
INTENDED USE:	The Pioneer Vertebral Spacer is intended for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Pioneer Vertebral Spacer is also indicated for treating fractures of the thoracic and lumbar spine. The Pioneer Vertebral Spacer is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The system must be used with the Pioneer Quantum Pedicle Screw System or supplemental internal fixation systems cleared for the conditions listed above (i.e., tumor or trauma of T1-L5). *Additionally, the Pioneer Vertebral Spacer implant is intended to be used with bone graft.*
MATERIAL:	Radiolucent polymer and titanium alloy materials in conformance with ASTM Standard Specifications.
PERFORMANCE DATA:	Mechanical and Chemical information were presented.
BASIS OF SUBSTANTIAL EQUIVALENCE:	The Pioneer Vertebral Spacer implants are substantially equivalent to the components of a previously cleared Pioneer spinal system, with similar materials, performance, and indications for use demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2006

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

Re: K061151
Trade/Device Name: Vertebral Spacer
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: June 8, 2006
Received: June 9, 2006

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.

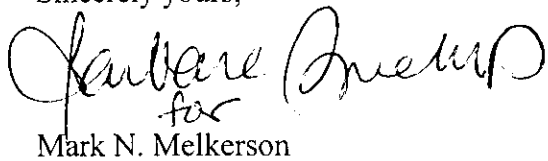
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for

Mark N. Melkerson
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 (if known): K061151

Device Name: PIONEER Vertebral Spacer

Indications for Use: The Pioneer Vertebral Spacer is intended for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Pioneer Vertebral Spacer is also indicated for treating fractures of the thoracic and lumbar spine. The Pioneer Vertebral Spacer is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The system must be used with the Pioneer Quantum Pedicle Screw System or supplemental internal fixation systems cleared for the conditions listed above (i.e., tumor or trauma of T1-L5). Additionally, the Pioneer Vertebral Spacer implant is intended to be used with bone graft.

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Carlos Bruno

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

510(k) Number K061151