

JAN 21 2005

## 510(k) Summary

**SPONSOR:** PIONEER SURGICAL TECHNOLOGY  
375 River Park Circle  
Marquette, MI 49855  
Contact: Jonathan M. Gilbert

**DEVICE NAME:** Pioneer 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:** EBI CAS Spine Spacer System K042268

**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 corpectomy.

**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). The interior of the Pioneer Vertebral Spacer implant can be packed with bone.

**MATERIAL:** Radiolucent polymer and titanium alloy materials in conformance with ASTM Standard Specifications.

**PERFORMANCE:** Mechanical and Chemical information were presented.

**BASIS OF SUBSTANTIAL EQUIVALENCE:** The Pioneer Vertebral Spacer implants are similar to the components of previously cleared spinal systems in terms of design, indications, performance and materials.



JAN 21 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K043206  
Trade/Device Name: PIONEER Vertebral Spacer  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: II  
Product Code: MQP  
Dated: November 18, 2004  
Received: November 19, 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.

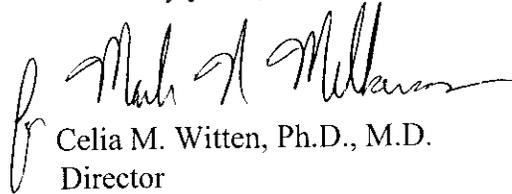
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "M".

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 (if known): K043206

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). The interior of the Pioneer Vertebral Spacer implant can be packed with bone.

Prescription Use   X   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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)  
*[Signature]*  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

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