K110367

MAR 2 3 2011

510(k) SUMMARY

Pioneer Spinous Process Fusion Plate

Sponsor:	Manufacturer	Pioneer Surgical Technology 375 River Park Circle Marquette, MI 49855
	Official Contact	Emily M. Downs
	Phone:	(906) 225-5602
	Fax:	(906) 226-4459
	Date prepared:	February 4, 2011
Device Name:	Pioneer BacFuse Spinous Process Fusion Plate	
Product Code/ Classification:	KWP/ 888.3050 – Spinal Interlaminal Fixation Orthosis	
Predicate Device:	Pioneer Spinous Process Fusion Plate (K101525, SE date 10/22/2010)	
Description:	The Pioneer Spinous Process Fusion Plate is a plate with spacer system designed to provide posterior fixation by physically linking adjacent spinous processes. The system also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.	
Intended Use:	The Pioneer BacFuse Device is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The Pioneer BacFuse Device is intended for use with bone graft material (i.e. allograft or autograft), not intended for stand-alone use.	
Material:	The Pioneer Spinous Process Fusion Plate is composed of Ti Alloy per ASTM F136. The predicate device is composed of the same material.	
Performance Data:	Static torsion, static tension, static compression, static locking mechanism, dynamic flexion-extension, and dynamic locking mechanism testing was performed on the representative worst case construct for each test mode. Results found the subject device to perform equivalent or superior to predicate devices.	

Comparison to Predicate Devices:	The indications for use of the Pioneer Spinous Process Fusion Plate are the same as the predicate device. Implant material, design characteristics, and mechanism of action for the Pioneer Spinous Process Fusion plate are identical to that of predicate systems.
SE Determination:	Equivalence for Pioneer Spinous Process Fusion System is based on similarities of intended use, design, and physical characteristics when compared to predicate devices. Therefore, Pioneer Surgical Technology believes that there is sufficient evidence to conclude that the Pioneer Spinous Process Fusion Plate System is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Pioneer Surgical Technology, Inc.
% Ms. Emily M. Downs
Regulatory Affairs Manager
375 River Park Circle
Marquette, Michigan 49855

MAR 2 3 2011

Re: K110367
Trade/Device Name: Pioneer Spinous Process Fusion Plate
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: March 10, 2011
Received: March 11, 2011

Dear Ms. Downs:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K11 0367

Device Name: Pioneer Spinous Process Fusion Plate

Indications:

The Pioneer BacFuse Device is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The Pioneer BacFuse Device is intended for use with bone graft material (i.e. allograft or autograft), not intended for stand-alone use.

Prescription Use √ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110367