K120016

510(k) Summary

JUL 26 2012

Sponsor:	Pioneer Surgical Technology 375 River Park Circle Marquette, MI 49855 (906) 225-5861 Contact: Sarah McIntyre or Emily Downs Prepared: July 25, 2012
Device Name:	Pioneer Sternal Assist Implant System
Classification:	Class II; JDQ, HRS 888.3030 – Plate, Fixation, Bone 888.3010 – Bone Fixation Cerclage Panel Code: 87
Predicate Devices:	K101170 ACUTE Innovations Acutie Sternal Fixation System (SE 9/17/10) K110789 Synthes ZipFix (SE 7/28/11) K935481 Pioneer Songer Cable System (SE 1/26/94) K931271/K946173 – Ethicon Stainless Steel Suture Wire (SE 1/9/95)
Intended Use:	The Pioneer Sternal Assist Implant System is intended for use in the stabilization and fixation of fractures of the anterior chest wall, including sternal fixation following sternotomy and sternal reconstructive surgical procedures.
Description:	The Pioneer Sternal Assist Implant System consists of implantable plates for use with the Pioneer Sternal Cable System or USP #5, 6, or 7 Stainless Steel wire as a supplemental fixation to provide fixation for sternotomies and sternal fractures. The components are made of PEEK (polyetheretherketone) per ASTM F2026. The purpose of this submission is to introduce a new sternal closure system to interstate commerce.
Performance Data:	Static and dynamic testing of the subject device was completed to demonstrate that performance related to strength and cut-through resistance was equivalent to or better than the predicate. Testing and engineering analysis were also provided to mitigate the risk of wear and show that no new issues of safety or effectiveness were raised.
Performance and SE Determination:	Equivalence for the Pioneer Sternal Assist Implant System is based on similarities of intended use, mechanical strength, design, and physical characteristics when compared to predicate devices. Therefore, Pioneer Surgical Technology believes that there is sufficient evidence to conclude that the Pioneer Sternal Assist Implant 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 –WO66-G609
Silver Spring, MD 20993-0002

Pioneer Surgical Technology, Incorporated
% Ms. Sarah McIntyre
Regulatory Affairs Associate
375 River Park Circle
Marquette, Michigan 49855

JUL 26 2012

Re: K120016
Trade/Device Name: Pioneer Sternal Assist Implant System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single / multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, JDQ
Dated: June 8, 2012
Received: June 12, 2012

Dear Ms. McIntyre:

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 Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 Indications for Use Statement

510(k) Number (if known): K12 0016

Device Name: Pioneer Sternal Assist Implant System

Indications: The Pioneer Sternal Assist Implant System is intended for use in the stabilization and fixation of fractures of the anterior chest wall, including sternal fixation following sternotomy and sternal reconstructive surgical procedures.

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 K120016