510(k) Summary Pursuant to 21 CFR 807.92

JAN 2014

Sponsor:
Pioneer Surgical Technology, Inc.
(RTI Surgical, Inc.)
375 River Park Circle
Marquette, MI 49855 USA
Contact: Emily Downs, Sarah McIntyre
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Prepared: January 2, 2014

Name: Pioneer Sternal Cable Plate System

Trade names: Tritium

Common name: Pioneer Sternal Cable Plate System

Classifications: §888.3010 Cerclage, Fixation, Metallic
§888.3030 Plate, Fixation, Bone, Non-Spinal, Metallic
§888.3040 Screw, Fixation, Bone, Non-Spinal, Metallic

Product Codes: JDQ, HRS, HWC

Panel/ Branch: Orthopaedic and Rehabilitation Devices Panel; Panel Code 87

Predicates: Pioneer Sternal Cable System (K122293)
Biomet SternaLock Blu Microfixation Sternal Closure System (K110574)
Ethicon Wire (K946173)

Description: The Pioneer Sternal Cable Plate System contains various configurations of plates, some with integrated cables and crimps, and Ø2.7mm and 3.0mm self-drilling screws (lengths 8-20mm) to allow for multiple anterior chest wall and sternal repair and reconstruction options. The implants are manufactured from medical grade ASTM F67 Grade IV commercially pure titanium and ASTM F136 Titanium alloy.

The implants may be implanted via an open or minimally invasive approach using Class I (exempt) orthopedic manual surgical instruments.

The purpose of this submission is to add additional implant configurations to the system.

Intended Use:	The Pioneer Sternal Cable Plate 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.
Pre-Clinical Performance Data:	Static and Dynamic Tensile Tests were provided to support that the Pioneer Sternal Cable Plate System performs in a manner substantially equivalent to that of predicate systems. No new issues of safety or effectiveness were raised.
Substantial Equivalence	This submission supports the position that the subject system is substantially equivalent to previously cleared systems. The subject and predicate systems are similar in terms of indications for use, material composition, sterilization, packaging, technological characteristics, design features, and mechanical strength. There are no significant differences between the subject system and the predicates which would adversely affect the use of the product. Any differences were not considered significant based on mechanical bench testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 27, 2014

Pioneer Surgical Technology, Incorporated (RTI Surgical, Incorporated)
Ms. Emily Downs
Director of Regulatory and Clinical Affairs
375 River Park Circle
Marquette, Michigan 49855

Re: K133785
Trade/Device Name: Pioneer Sternal Cable Plate System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ, HRS, HWC
Date: January 2, 2014
Received: January 3, 2014

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Vincent D Devlin -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)* K133785

Device Name
Pioneer Sternal Cable Plate System

Indications for Use *(Describe)*
The Pioneer Sternal Cable Plate 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth A. Frank -S

Division of Orthopedic Devices