



Food and Drug Administration
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June 4, 2015

Pioneer Surgical Technology, Incorporated (dba RTI Surgical, Incorporated)
Ms. Sarah Pleaugh
Regulatory Affairs Specialist
375 River Park Circle
Marquette, Michigan 49855

Re: K150581

Trade/Device Name: Tritium Sternal Cable Plate System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ, HRS, HWC
Dated: March 6, 2015
Received: March 9, 2015

Dear Ms. Pleaugh:

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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 -S

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K150581

Device Name

Tritium Sternal Cable Plate System

Indications for Use (Describe)

The Tritium 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
As required by 21 CFR 807.92
K150581

Sponsor:	<p>Pioneer Surgical Technology, Inc. (DBA RTI Surgical, Inc.) 375 River Park Circle Marquette, MI 49855 USA</p> <p>Contact: Sarah Pleaugh Phone: (906) 225-5861 Fax: (906) 226-4459</p> <p>Prepared: May 1, 2015</p>
Trade name:	Tritium Sternal Cable Plate System
Common name:	Sternal Cable Plate System
Classification:	<p>Class II</p> <p>888.3010 Cerclage, Fixation, Metallic</p> <p>888.3030 Plate, Fixation, Bone, Non-Spinal, Metallic</p> <p>888.3040 Screw, Fixation, Bone, Non-Spinal, Metallic</p>
Product Codes/ Panel:	<p>JDQ, HRS, HWC</p> <p>Panel Code 87</p>
Predicates:	<p>K133785 Pioneer Tritium Sternal Cable Plate System</p> <p>K110574 Biomet SternaLock Blu Microfixation Sternal Closure System</p> <p>K935481 Pioneer Sternal Cable System</p>
Description:	<p>The Tritium 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 to aid in the alignment and stabilization of bone. The Sternal Cable Plate System can be used with traditional monofilament wire or Pioneer Sternal Cable. Instrumentation has been designed specifically for use with this system of implants, which may be implanted via an open or minimally invasive approach.</p> <p>The purpose of this submission is to add an additional implant to the predicate Tritium Sternal Cable Plate System.</p>
Materials:	<p>The Tritium System components are manufactured from ASTM F-67 Commercially Pure (CP) Titanium and ASTM F-136 Titanium 6Al 4V Alloy. CP Titanium and medical grade titanium alloy may be used together.</p>
Intended Use:	<p>The Tritium 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.</p>

Technological Characteristics:	<p>The subject components are overall similar in technological characteristics as compared to the predicates in terms of:</p> <ul style="list-style-type: none"> - Basic design: screws and plates of various sizes and configurations, threaded plate-screw interface, may be used with cerclage (e.g. wire or cable) - Materials: CP titanium and titanium alloy - Design: sizes and dimensions equivalent or comparable to predicates <p>There are no significant differences between the subject and predicate devices' technological characteristics which would raise new issues of safety or effectiveness.</p>
Non-Clinical Performance Data:	<p>The determination of substantial equivalence was based on worst-case engineering analysis and non-clinical performance testing, which included static and dynamic tensile strength testing. Non-clinical performance testing concluded the subject product is expected to be as safe, as effective, and perform as well as or better than the predicate.</p>
Clinical Performance Data:	<p>The determination of substantial equivalence was not based on clinical performance data.</p>
Substantial Equivalence:	<p>The subject system is substantially equivalent to previously cleared anterior chest wall fixation systems based on comparison of intended use, materials, design, technological characteristics, and performance.</p>