DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 9, 2016

Pioneer Surgical Technology, Inc.
% Ms. Sarah Pleaugh
Regulatory Affairs Specialist
DBA RTI Surgical, Inc.
375 River Park Circle
Marquette, Michigan 49855

Re: K161876
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: August 18, 2016
Received: August 19, 2016

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 Parts 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,

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

Indications for Use

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

510(k) Number *(if known)*
K161876

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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K161876

510(k) Summary

As required per 21 CFR Section 807.92

Prepared:	September 8, 2016
510(k) Owner / Manufacturer:	Pioneer Surgical Technology, Inc. DBA RTI Surgical, Inc. 375 River Park Circle Marquette, MI 49855 USA Telephone: 906-226-9909 Fax: 906-225-5868
Contact Person:	Sarah Pleaugh, RAC Regulatory Affairs Specialist
Device trade/ proprietary name:	Tritium® Sternal Cable Plate System
Common name:	Sternal Cable Plate System
Classification regulation:	888.3010; Cerclage, Fixation, Metallic 888.3030; Plate, Fixation, Bone, Non-Spinal, Metallic 888.3040; Screw, Fixation, Bone, Non-Spinal, Metallic
Device class:	Class II
Product code:	JDQ, HRS, HWC
Review panel:	Panel Code 87; Orthopedic
Predicate device:	K150581 Tritium Sternal Cable Plate System
Description:	The Tritium Sternal Cable Plate System includes implants of various sizes; plates and cable plugs comprised of commercially pure titanium, Grade IV (ASTM F67), and cables and screws comprised of Titanium 6AI 4V Alloy (ASTM F136). The system also includes needles comprised of Custom 470 stainless steel, 420 stainless steel (ASTM F899, Custom 470 SST) and leader comprised of Titanium 3AI/ 2.5V Alloy (ASTM F2146). The system is designed to enhance the stability and strength of traditional sternal closure techniques. Utilizing a unique load-sharing concept, the device can be implanted to distribute lateral force across the osteotomy. The system can be used with traditional monofilament wire or Pioneer Sternal Cable. The device system should be implanted using only the manual surgical instruments designed specifically for this system of implants, which may be implanted via an open or minimally invasive approach.

Purpose of this submission:	The purpose of this submission is to obtain clearance of modifications (line extensions) to the predicate system (K150581).
Intended Use/ Indications for Use:	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.
Technological characteristics:	The subject system has the same or similar technological characteristics (overall design, material, principles of operation, and anatomical location of use) as the predicate. The subject modifications do not impact the technological characteristics as compared to K150581.
Non-Clinical Performance Data:	Engineering analysis was completed for the subject line extension product and demonstrated no new performance data was required for a determination of substantial equivalence. Pyrogenicity will be evaluated using the Limulus amebocyte lysate (LAL) assay. The device will be tested to ensure the endotoxin level meets the requirements of maximum endotoxin limit for implantable medical devices [20 EU per device].
Clinical Performance Data:	No clinical performance data was required for a determination of substantial equivalence.
Substantial Equivalence:	The subject line extension product is substantially equivalent to previously cleared anterior chest wall fixation systems based on comparison of intended use, materials, minimum number of screw holes per sternal half, screw hole geometry, cable/ needle/ leader/ plug geometry design, technological characteristics, mechanical strength and performance. The modifications to the predicate K150581 system do not raise new issues of safety or effectiveness.