March 12, 2020

Pioneer Surgical Technology, Inc. (dba RTI Surgical, Inc.)
% Peter Browne
RA Specialist
A&E Medical Corporation
5206 Asbury Road, PO BOX 758
Farmingdale, New Jersey 07727

Re: K193468
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: December 10, 2019
Received: December 16, 2019

Dear Peter Browne:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Ronald P. Jean, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193468

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

Date Prepared	December 10th, 2019
510(k) Owner/ Manufacturer:	Pioneer Surgical Technology, Inc. dba RTI Surgical, Inc. 375 River Park Circle Marquette, MI 49855 USA http://www.rtix.com Establishment Registration #1833824
Contact Person/Consultant:	Peter Browne - RA Specialist A&E Medical Corporation Phone: (732) 378-7337 Fax: (732) 938-2399 Email: p.browne@aemedical.com
Trade name:	Tritium® Sternal Cable Plate System
Common name:	Sternal Cable Plate System
Classification:	Class II; JDQ; 21 CFR 888.3010; Cerclage, Fixation HRS; 21 CFR 888.3030; Plate, Fixation, Bone HWC; 21 CFR 888.3040; Screw, Fixation, Bone
Panel:	Panel Code 87
Predicate:	K161876 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 submission:	Obtain clearance for the following modification to the predicate K161876 Tritium® Sternal Cable Plate System: add magnetic resonance (MR) conditional safety labeling based on completed non-clinical testing.
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.

Summary of Technological Characteristics:	The subject Tritium® Sternal Cable Plate System has the same technological characteristics as the predicate K161876 devices cleared for use in closure of the sternum. Similarities to the predicate device include: - Same indications for use within cardiovascular surgery applications - Same materials, manufacturing processes and biocompatibility: metallic devices, stainless steel and titanium - Same principles of operation and fundamental technology: intended to stabilize and fixate fractures of the anterior chest wall (e.g. sternal fixation) through the use of plates, screws that lock into system plates, and integrated cable sub-assemblies - Same instrumentation: trial plates, screw sizer, cable and plate cutters, tensioner, crimper, screw driver, sterilization case and caddy - Same general surgical technique method: - Same sterility and shelf life: gamma irradiation (sterile implants) and steam sterilization by the user (non-sterile implants and instruments) - Same packaging: double sterile barrier (sterile implants) and polybag/carton (non-sterile implants and instruments) - Same bacterial endotoxin evaluation and limit (20 EU/device) - Same mechanical performance - Same screw features and cable subassembly components The modification to the labeling is supported by non-clinical testing listed below.
Discussion of Supporting Clinical Evidence and Non-Clinical Testing:	The following nonclinical tests were submitted and relied on in this premarket notification submission for a determination of substantial equivalence. Testing identified in this summary has all passed acceptance criteria established by the predicate device where applicable. MR Safety Evaluation following standards listed below: • ASTM F2052-15, “Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment” • ASTM F2213-17, “Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment” • ASTM F2182-11a, “Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging” • ASTM F2119-07 (Reapproved 2013), “Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants”
Conclusion	The subject Tritium® Sternal Cable Plate System was shown to be substantially equivalent to the predicate system. The devices are determined to be MR Conditional based on the results of testing completed according to FDA Guidance document "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", December 11, 2014.