February 12, 2018

A&E Medical Corporation
% Sarah Pleaugh
Regulatory Affairs Specialist
RTI Surgical Inc.
375 River Park Circle
Marquette, Michigan 49855

Re: K173579
Trade/Device Name: Thorecon™ Fixation System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ, HRS, HWC, GAQ
Dated: January 22, 2018
Received: January 24, 2018

Dear Sarah 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173579

Device Name
Thorecon Fixation System

Indications for Use *(Describe)*

The Thorecon Fixation 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. The system is intended for use in patients with normal and/or poor bone quality.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Prepared on: February 12, 2018

510(k) Owner/ Manufacturer:	A&E Medical Corporation 5206 Asbury Road, PO Box 758 Farmingdale, NJ 07727 USA
Contact Person/ Consultant:	Sarah Pleaugh, RAC Sr. Specialist, Regulatory Affairs RTI Surgical, Inc. Telephone: 1(906)226-9909 x 5861 Fax: (386) 418-1627 Email: spleaugh@rtix.com
Trade name:	Thorecon™ Fixation System
Common name:	Sternal Fixation System
Classification:	Class II; 21 CFR 888.3010 (JDQ, Cerclage, Fixation) 21 CFR 888.3030 (HRS, Plate, Fixation, Bone) 21 CFR 888.3040 (HWC, Screw, Fixation, Bone) 21 CFR 878.4495 (GAQ, Suture, Nonabsorbable, Steel, Monofilament and multifilament, Sterile)
Panel:	Panel Code 87
Predicates:	K161876 Tritium Sternal Cable Plate System K931271 Ethi-pack Surgical Stainless Steel Suture K151019 SternaLock 360 Sternal Closure System K150581 Tritium Sternal Cable Plate System K111908 Biomet Microfixation Sternal Closure System K974016 Cerclage Cable with Hex Button (REFERENCE) K935481 Songer Cable System, Modification (REFERENCE)
Description:	The Thorecon Fixation System may be implanted via an open or minimally invasive approach. Where additional stability is desired, devices can be used with traditional monofilament wire or Pioneer Sternal Cable of similar material. The Thorecon Fixation System includes plates (some with integrated cable subassemblies) manufactured from 316L stainless steel (ASTM F138) and screws comprised of 22Cr-13Ni-5Mn stainless steel (ASTM F1314). Non-implantable needles, used to guide the cable around the sternum are manufactured from 420 or Custom 470 stainless steel. Thorecon Fixation System devices are all single-use. The plates, complete with the necessary screws and instruments (screw driver and tensioner/cutter) required for completion of the surgery, are

	provided sterile in a kit. Sterile instruments and screw multi-packs and a non-sterile cable/ plate cutter instrument are also available as replacements and for use during emergent re-entry, if necessary. The devices should be implanted using only the manual surgical instruments designed specifically for the implants in the system.
Indications for Use:	The Thorecon Fixation 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. The system is intended for use in patients with normal and/or poor bone quality.
Summary of Technological Characteristics:	The subject devices were found to have similar technological characteristics as the predicate devices. Similarities to the predicate device include: ▪ Same intended use/ indications for use and contraindications ▪ Similar materials (metallic, stainless steel) ▪ Similar principles of operation and fundamental technology (plates, pre-assembled cerclage(s) and/or screws for fracture fixation) ▪ Similar instrumentation (e.g. screw driver, cable tensioner, cutters) ▪ Same general surgical technique method (sizing, cable insertion, approximation, tensioning, screw placement, final locking, removal of excess cerclage, closure; emergent re-entry available if necessary) ▪ Same sterility (gamma irradiation) and packaging (double sterile barrier) ▪ Same bacterial endotoxin evaluation and limit (20 EU/device) ▪ Similar / substantially equivalent mechanical performance There are minor differences in the design of the device and subject package configurations. However, the non-clinical testing completed supports that these differences do not raise different questions of safety or effectiveness.
Discussion of Supporting Clinical Evidence and Non-Clinical Testing:	No clinical evidence was provided in this submission. 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 predicate devices or test standards. <u>Mechanical Performance</u> ▪ Screw Push-Out of Plate Force Test ▪ Bone Screw Twist-Out of Plate Test

	▪ Bone Screw Pull-Out Test per ASTM F543 ▪ Static Tension Testing ▪ Dynamic Tension Testing <u>Packaging, Sterility and Shelf Life Validations completed per:</u> ▪ ISO 11607 Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems ▪ ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems ▪ ISO 11137-2 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose ▪ ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices ▪ ISO 17665-1 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices <u>Biocompatibility Evaluation per:</u> ▪ ISO 10993 Biological evaluation of medical devices – Parts 1, 5, 10, and 11 <u>Pyrogenicity Evaluation</u> Pyrogenicity of the sterile devices was evaluated using the Limulus amebocyte lysate (LAL) assay. The device was tested to ensure the endotoxin level meets the requirements of maximum endotoxin limit for implantable medical devices [20 EU per device].
Conclusion:	The supporting evidence in this submission concludes the subject Thorecon Fixation System is substantially equivalent to the predicate devices. There are no new risks to safety or effectiveness raised.