A&E Medical Corporation

% Sarah Pleaugh
Regulatory Affairs Sr. Specialist
RTI Surgical, Inc
375 River Park Circle
Marquette, Michigan 49855

Re: K181607

Trade/Device Name: Thorecon™ Rigid Fixation System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ, HRS, HWC, GAQ
Dated: June 15, 2018
Received: June 19, 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. 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/cfpmm/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
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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Daniel S. Ramsey -S

2018.10.12 15:35:25 -04'00'

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

Enclosure
Indications for Use

510(k) Number (if known)
K181607

Device Name
Thorcon Rigid Fixation System

Indications for Use (Describe)
The Thorcon Rigid 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.

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# 510(k) Summary

Prepared on: June 15, 2018

| 510(k) Owner/Manufacturer: | A&E Medical Corporation  
5206 Asbury Road, PO Box 758  
Farmingdale, NJ 07727 USA |
|---------------------------|---------------------------------------------------------------------|
| Contact Person/Consultant: | Sarah Pleugh, RAC  
Sr. Specialist, Regulatory Affairs  
RTI Surgical, Inc.  
Telephone: 1(906)226-9909 x 5861  
Fax: (386) 418-1627  
Email: spleauhg@rtix.com |
| Trade name: | Thorecon™ Rigid 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 |
| Predicate: | K173579 Thorecon Fixation System |
| Description: | The Thorecon Rigid 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 Sternal Cable of similar material.  
The Thorecon Rigid 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 devices are all single-use. The plates, complete with the necessary screws and instruments (torque driver and tensioner/cutter) required for completion of the surgery, are provided sterile in a disposable 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 Rigid 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.

### Purpose of Submission:
To obtain clearance of modifications to the Thorecon Rigid Fixation System, including the addition of MR Conditional Safety Labeling.

### Summary of Technological Characteristics:
The subject devices have the same technological characteristics as the predicate K173579, including:
- intended use/indication for use and contraindications
- materials (metallic, stainless steel)
- principles of operation and fundamental technology (plates, pre-assembled cerclage(s) and/or screws for fracture fixation)
- instrumentation (e.g. torque driver, cable tensioner, cutters)
- surgical technique method (sizing, cable insertion, approximation, tensioning, screw placement, final locking, removal of excess cerclage, closure; emergent re-entry available if necessary)
- sterility (gamma irradiation) and packaging (double sterile barrier)
- bacterial endotoxin evaluation and limit (20 EU/device)
- substantially equivalent mechanical performance

The modifications in labeling and design are supported by non-clinical testing listed below.

### Discussion of Supporting 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.

#### Mechanical Performance
- Worst-Case Construct Assessment
- Assessment of previously completed testing
- Cerclage Dynamic Tension Testing

#### MR Safety Evaluation following standards listed below:
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<th>Conclusion: The subject Thorecon Rigid Fixation 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 &quot;Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment&quot;, December 11, 2014.</th>
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