March 23, 2020

A&E Medical Corporation
Peter Browne
RA Specialist
5206 Asbury Road, PO Box 758
Farmingdale, New Jersey 07727

Re: K193479
Trade/Device Name: Sternal Cable System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: February 28, 2020
Received: March 2, 2020

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,

Colin O’Neill, MBE
Acting Assistant Director
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)*
K193479

Device Name
Sternal Cable System

Indications for Use *(Describe)*
Cardiovascular surgery - closure of the sternum following sternotomy.

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:	A&E Medical Corporation 5206 Asbury Road, PO Box 758 Farmingdale, NJ 07727 USA Establishment Registration #: 2242056
Contact Person:	Peter Browne - RA Specialist A&E Medical Corporation Phone: (732) 378-7337 Fax: (732) 938-2399 Email: p.browne@aemedical.com
Trade name:	Sternal Cable System
Common name:	Sternal Cable System
Classification:	Class II; JDQ; 21 CFR 888.3010; Cerclage, Fixation
Panel:	Panel Code 87
Predicate:	K180582 Sternal Cable System
Description:	The Sternal Cable System is an alternative over traditional monofilament sternal wire used for cardiovascular sternal closure following sternotomy. The system consists of multi-strand stainless steel and titanium cables and crimps, which are tensioned and secured around the bone using a tensioner/crimper instrument. Multiple "figure 8" constructs work as one unit to provide stabilization. Cables are manufactured from titanium 6Al-4V ELI alloy (ASTM F136) or 316L stainless steel (ASTM F138); CP titanium (ASTM F67) or 316L stainless steel (ASTM F138) crimps are provided to match the corresponding cable materials. However, the different metals are never to be mixed. Non-implantable leaders are manufactured from 316L stainless steel (ASTM F138) or titanium 3Al/2.5V Alloy (ASTM B863) and needles are 420 or 470 stainless steel. The implants are provided sterile for single-use but must never be re-sterilized; reusable instruments are supplied non-sterile and must be steam sterilized by the user prior to use in accordance with the instructions for use. Cases are supplied for sterilization and transport of the instruments.
Purpose of submission:	Obtain clearance for the following modification to the predicate K180582 Sternal Cable System: add magnetic resonance (MR) conditional safety labeling based on completed non-clinical testing.
Indications for Use:	Cardiovascular surgery - closure of the sternum following sternotomy.

Summary of Technological Characteristics:	The subject Sternal Cable System has the same technological characteristics as the predicate K180582 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: o Cable and crimp cerclages built in "figure 8" constructs to close the sternum following sternotomy o Cables are provided with a preassembled needle and leader which are used to facilitate intra-operative placement, but are removed prior to wound closure o Cables are tensioned then secured using crimps - Same instrumentation: tensioner/crimper, torque wrench, crimp holder, and cable cutter - Same general surgical technique method: pass cable around sternum then through crimp, tension cable, secure crimps, remove excess cable. Emergent re-entry available if necessary, using cutters. - Same sterility and shelf life: gamma irradiation (implants) and steam sterilization by the user (non-sterile instruments) - Same packaging: double sterile barrier (implants) and polybag (non-sterile 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 nonclinical 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 Sternal Cable 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.