Pioneer Surgical Technology, Inc. (DBA RTI Surgical, Inc.)
% Jaclyn Holli
Regulatory Affairs Specialist
RTI Surgical, Inc
375 River Park Circle
Marquette, Michigan 49855

October 28, 2020

Re: K201497
Trade/Device Name: EVOS Cabling System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: October 9, 2020
Received: October 13, 2020

Dear Jaclyn Holli:

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; Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201497

Device Name
EVOS Cabling System

Indications for Use *(Describe)*
The EVOS Cabling System is intended to be used in general orthopaedic repair procedures including patellar fractures, general cerclage, trochanteric reattachment, femoral and tibial fractures, prophylactic banding, olecranon fractures, ankle fractures, fixation of spiral fractures in conjunction with intramedullary nail and screw fixation techniques.

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 per 21 CFR 807.92

EVOS Cabling System

Date Prepared	October 27, 2020
510(k) Owner/ Manufacturer	Pioneer Surgical Technology, Inc. (DBA RTI Surgical, Inc.) 375 River Park Circle Marquette, MI 49855, USA Registration #1833824
Submitter/Contact Person	Jaclyn Holli – Regulatory Affairs Specialist RTI Surgical, Inc. Phone: 1.906.226.9909 Email: jholli@rtix.com
Trade Name of Device	EVOS Cabling System
Common Name	Cerclage, Fixation
Classification Name	Bone Fixation Cerclage
Classification	Class II per 21 CFR 888.3010 Product code JDQ
Panel	Orthopedic Device Panel
Predicate	Primary Predicate: Orthopedic Cabling System (K031162) Additional Predicate: SDB Cerclage System (K992616)
Description of Device	The EVOS Cabling System is used in orthopedic trauma and reconstructive surgeries to reduce and stabilize fractures and osteotomies. The EVOS Cabling System may be used for supplementary fracture fixation when used with bone plates or screws. The EVOS Cabling System includes a sterile, stainless-steel cable implant (ASTM F1314) packaged together with a stainless-steel crimp (ASTM F138). Non-sterile, reusable instruments are also provided to facilitate proper implantation of the cable-crimp implant.
Purpose of Submission	To obtain FDA Clearance of the EVOS Cabling System. There are no prior submissions for the subject system.

Indications for Use	The EVOS Cabling System is intended to be used in general orthopaedic repair procedures including patellar fractures, general cerclage, trochanteric reattachment, femoral and tibial fractures, prophylactic banding, olecranon fractures, ankle fractures, fixation of spiral fractures in conjunction with intramedullary nail and screw fixation techniques.
Summary of Technological Characteristics	The subject EVOS Cabling System has the same intended use and technological characteristics as the predicates and the following similarities: • Fundamental technology and intended uses: orthopedic cable cerclage to reduce and stabilize fractures for bone fixation • Overall design: multistrand, bundled cable with a mechanism to resist tension and lock the construct (crimp or clamp cerclage) • Principles of operation (cable passage around bone, cerclage tensioning and fixation) • Materials: metallic, stainless steel alloys with well-established manufacturing processes and biological safety • Sterility: sterile via gamma radiation • Single Use, Rx only • Packaging: double sterile barrier packaging with a 5-year shelf life • Mechanical performance sufficient to perform its intended use • Same instrumentation types The minor differences in the design characteristics do not raise different issues of safety or effectiveness as evidenced by the non-clinical testing. The subject EVOS Cabling System will be labeled as magnetic resonance (MR) conditional for which performance testing has been submitted for support of this claim. There are no other differences in technological characteristics between the subject and predicate devices.

Discussion of Supporting Clinical Evidence and Non-Clinical Evidence	The following non-clinical evidence was submitted and relied upon for a determination of substantial equivalence:
	• Mechanical performance: static and dynamic tensile testing of the construct strength.
	• MR Safety evaluation determined the devices are MR Conditional via the following standard methods:
	  ○ 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 • Implant packaging and sterilization testing and evaluations, relying on equivalency to predicate device design and package configuration • Instrument (and case components that keep the instruments in place during transit and sterilization) sterilization testing and evaluations, relying on subject validation testing • ISO 10993-1 Biological safety evaluation, relying on material and manufacturing process equivalency to predicate devices. • Pyrogenicity evaluation of the devices based on current industry practice and FDA guidance for batch release testing: endotoxin limit of 20 EU per device using the Limulus amebocyte lysate (LAL) assay. There are no clinical tests relied on in this premarket notification submission for a determination of substantial equivalence.
Conclusion	The evidence provided in this premarket notification submission supports substantial equivalence of the subject EVOS Cabling System to the predicate devices.