October 29, 2026

Pioneer Surgical Technology, Inc. dba EXALTA Group
Michelle Lemieux
Regulatory Specialist
375 River Park Cir.
Marquette, Michigan 49855

Re: K262960
Trade/Device Name: Cerclage Cabling System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: August 24, 2026
Received: August 25, 2026

Dear Michelle Lemieux:

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding

When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

THOMAS MCNAMARA -S

For: Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262960

Please provide the device trade name(s).

Cerclage Cabling System

Please provide your Indications for Use below.

1.1mm Needle Cable Indications:
The 1.1mm cerclage cable is indicated for use in adults and adolescents with closed growth plates to allow for supplementary cerclage fixation with orthopedic fracture fixation devices and to stabilize bone graft material.

1.6mm, 2.0mm Standard Open Cable and 2.0mm Lay Flat (MIS) Cable Indications:
The 1.6mm standard cerclage cable, 2.0mm standard cerclage cable and 2.0mm MIS cerclage cables are indicated for use in adults and adolescents with closed growth plates patients to allow for supplementary cerclage fixation with orthopedic fracture fixation devices and to stabilize bone graft material.

The Stryker Cerclage can also be used in adults and adolescents with closed growth plates to reattach the greater trochanter after trochanteric osteotomy during total hip arthroplasty.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

Device Trade Name:	Cerclage Cabling System
Manufacturer:	Pioneer Surgical Technology, Inc. 375 River Park Circle Marquette, MI 49855
Contact:	Michelle LeMieux Regulatory Specialist Pioneer Surgical Technology, Inc.
Date Prepared:	October 14, 2026
Panel:	Orthopedic
Class:	II
Product Codes:	JDQ
Regulation:	21 CFR 888.3010
Primary Predicate:	Howmedica Dall-Miles Recon and Trauma Cable System (K202016)
Reference Device:	EVOS Cabling System (K201497)
Reference Device:	Synthes Orthopedic Cabling System (K992616)

Indications For Use:

1.1mm Needle Cable Indications:

The 1.1mm cerclage cable is indicated for use in adults and adolescents with closed growth plates to allow for supplementary cerclage fixation with orthopedic fracture fixation devices and to stabilize bone graft material.

1.6mm, 2.0mm Standard Open Cable and 2.0mm Lay Flat Cable Indications:

The 1.6mm standard cerclage cable, 2.0mm standard cerclage cable and 2.0mm Lay Flat cerclage cables are indicated for use in adults and adolescents with closed growth plates to allow for supplementary cerclage fixation with orthopedic fracture fixation devices and to stabilize bone graft material.

The Stryker Cerclage can also be used in adults and adolescents with closed growth plates to reattach the greater trochanter after trochanteric osteotomy during total hip arthroplasty.

Device Description:
The Cerclage Cabling System includes Implants and Instruments. The Cerclage Cable Implants include a variety of Cerclage Cables (1.1mm needle cable, 1.6mm, 2.0mm, 2.0mm Lay Flat) and Crimps that are intended for supplementary fixation of fractures with orthopedic fracture fixation devices and to stabilize bone graft. The 1.6mm, 2.0mm, and 2.0mm Lay Flat Cables may be used to reattach the greater trochanter after trochanteric osteotomy during total hip arthroplasty.

The Cerclage Cabling Implants are provided sterile and the Instruments are provided non-sterile and may be reused following the provided reprocessing instructions.

Differences in Technological Characteristics:
The subject device has similar technological characteristics to the cited predicate and reference devices. The subject device, predicate device, and reference device cerclages are manufactured from cobalt chrome alloys and are offered in the same sizes.

Performance Testing Summary:
The following tests were conducted to demonstrate substantial equivalence:

- Static and Dynamic Testing
- Compatibility Testing
- MR Testing
- Biocompatibility Assessment per ISO 10993-1
- Sterilization Validation
- Packaging Validation
- Shelf-Life Validation

The subject devices met the pre-determined acceptance criteria for all tests and assessments.

Substantial Equivalence:
The data presented within the subject 510(k) demonstrates that the Cerclage Cabling System is substantially equivalent to the cited predicate devices. The subject, predicate, and reference devices have the same intended use, fundamental scientific technology, incorporate the same materials and have the same principles of operation.

Conclusion:
The Cerclage Cabling System is substantially equivalent to the legally marketed predicate devices