July 16, 2026

Pioneer Surgical Technology, Inc.
Sravyalahari Sripada
Sr. Regulatory Specialist
375 River Park Cir.
Marquette, Michigan 49855

Re: K261271
Trade/Device Name: Cable-Ready® Cable Grip System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ, KTT, HTN, HRS, HWC
Dated: April 16, 2026
Received: April 17, 2026

Dear Sravyalahari Sripada:

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.

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,

CHRISTOPHER FERREIRA -S

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.

K261271

Please provide the device trade name(s).

Cable-Ready® Cable Grip System

Please provide your Indications for Use below.

Cerclage Cable with Crimp
The Cerclage Cable with Crimp is indicated for use in skeletally mature patients to secure fractures of the olecranon, patella, femur, and humerus. The Cerclage Cable with Crimp can also be used in skeletally mature patients to reattach the greater trochanter after trochanteric osteotomy during total hip arthroplasty.

Needle Cable
The Needle Cable is indicated for use in skeletally mature patients for securing fractures of the olecranon, patella, and humerus.

Cable Pin
The Cable Pin is indicated for use in skeletally mature patients for olecranon fractures, patellar fractures, proximal humerus fractures, and greater tuberosity humerus fractures.

Bone Plate with Cerclage Cable
The Bone Plate with Cerclage Cable is indicated for use in skeletally mature patients where wire, cable, or band cerclage is used in combination with bone plates to provide fixation and/or stabilization of long bones. Examples include periprosthetic fractures or bone loss, comminuted shaft fractures, and nonunions of previous fractures with or without failed hardware.

Greater Trochanter Reattachment (GTR) Device and GTR Cable
The Greater Trochanter Reattachment (GTR) Device (including cables) is indicated for use in skeletally mature patients for the reattachment of the greater trochanter following osteotomy in total hip replacement and for fracture of the greater trochanter. The Extended GTR is additionally indicated for use in skeletally mature patients for reattachment of the greater trochanter in periprosthetic fractures of the femur.

Hex Button
The Hex Button is an optional accessory that, when used with a cerclage cable/wire, is indicated for use in skeletally mature patients for the following:
• prevent cable migration and screw backout when interfaced with a screw
• prevent cable migration when interfaced with a locking cap or plate

Please select the types of uses (select one or both, as applicable).

- [x] 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)
- [x] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(k) #: **K261271**

510(k) Summary

Prepared on: 2026-04-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Pioneer Surgical Technology, Inc.
Applicant Address	375 River Park Cir Marquette MI 49855 United States
Applicant Contact Telephone	906.226.9909
Applicant Contact	Mrs. Sravyalahari Sripada
Applicant Contact Email	ssripada@exalta.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Cable-Ready® Cable Grip System
Common Name	Bone fixation cerclage, 888.3030 -Single/multiple component metallic bone fixation appliances and accessories , 888.3040 - Smooth or threaded metallic bone fixation fastener
Classification Name	Cerclage, Fixation
Regulation Number	888.3010
Product Code(s)	JDQ, KTT, HTN, HRS, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K151907	Cable-Ready® Cable Grip System: Cable-Ready® 1.8mm Cerclage Cables	JDQ
K992617	Hex Button	HTN
K000734	PIONEER SURGICAL TECHNOLOGY EXTENDED GTR	KTT
K151907	Cable-Ready® Cable Grip System: Cable-Ready® GTR System	KTT
K151716	Cable-Ready® Cable Grip System: Cable-Ready Bone Plate System	HRS
K151848	Cable-Ready® Cable Grip System: Cable-Ready Pin System	HWC
K151848	Cable-Ready® Cable Grip System: Cable-Ready Needle System	JDQ

Device Description Summary

21 CFR 807.92(a)(4)

The Cable-Ready Cable Grip System includes the following sterile, single-use implantable devices: Cerclage Cable with Crimp, Needle Cable, Cable Pin, Bone Plate with Cerclage Cable, Greater Trochanter Reattachment (GTR) Device and GTR Cable, and optional accessory Hex Button. Only implants and instruments designed for use with this system should be used. Instrument use and implantation/ explantation of the Cable-Ready Cable Grip System implants should be performed by experienced orthopedic surgeons in an operating

room environment. Cable-Ready devices provide fracture reduction and temporary restoration of structural integrity to promote bone fusion. The Bone Plate and GTR Devices provide internal (within the bone) and external (outside the bone) fixation when used in combination with cables and bone screws. The Bone Plate and GTR Devices can provide fixation when a prosthesis occupies the bone cavity and bone screws are not appropriate. Cable-Ready devices are manufactured from durable biocompatible materials.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

Cerclage Cable with Crimp
The Cerclage Cable with Crimp is indicated for use in skeletally mature patients to secure fractures of the olecranon, patella, femur, and humerus. The Cerclage Cable with Crimp can also be used in skeletally mature patients to reattach the greater trochanter after trochanteric osteotomy during total hip arthroplasty.

Needle Cable
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Cable Pin
The Cable Pin is indicated for use in skeletally mature patients for olecranon fractures, patellar fractures, proximal humerus fractures, and greater tuberosity humerus fractures.

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Hex Button
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• prevent cable migration when interfaced with a locking cap or plate

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject Cable-Ready Cable Grip System indications for use add reference to patient population and as applicable, reduce indications.

Technological Comparison 21 CFR 807.92(a)(6)

The subject devices and the primary predicate devices are the same device with respect to intended use, design, materials, and technological characteristics. The subject devices differ only by updates to changes in manufacturer (labeling), packaging, shelf-life, and addition of MR conditional labeling. These updates do not alter the intended use or fundamental technological characteristics.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

MR Safety analysis and testing was conducted per ASTM F2052, ASTM F2182 and ASTM F2213 to support MR Conditional labeling.

Clinical Data - Not Applicable

MR Safety analysis and testing supports MR Conditional labeling.