April 28, 2022

Pioneer Surgical Technology, Inc D.B.A Resolve Surgical Tech
Jaclyn Holli
Sr. Specialist, Regulatory Affairs
375 River Park Circle
Marquette, Michigan 49855

Re: K220244
Trade/Device Name: DVR® Crosslock Wrist Spanning Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: January 27, 2022
Received: January 28, 2022

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,

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)*
K220244

Device Name
DVR® Crosslock Wrist Spanning Plate

Indications for Use *(Describe)*
The DVR® Crosslock Wrist Spanning Plate is indicated for skeletally mature patients for fixation of fractures, osteotomies and non-unions of the distal radius.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Prepared on: 2022-04-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Pioneer Surgical Technology, Inc D.B.A Resolve Surgical Technologies
Applicant Address	375 River Park Circle Marquette MI 49855 United States
Applicant Contact Telephone	9062269909
Applicant Contact	Ms. Jaclyn Holli
Applicant Contact Email	jholli@resolvesurg.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	DVR® Crosslock Wrist Spanning Plate
Common Name	Single/multiple component metallic bone fixation appliances and accessori
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code	HRS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K143749	Arthrex Distal Radius System	HRS
K000734	Extended GTR Device	KTT
K211408	CervAlign® Anterior Cervical Plate System	KWQ
K111528	PIONEER ASPECT ANTERIOR CERVICAL PLATE MODEL 24	KWQ

Device Description Summary

21 CFR 807.92(a)(4)

The DVR® Crosslock Wrist Spanning Plate is a single-use plate for the fixation of fractures, osteotomies and non-unions of the distal radius. The plate spans the patient's wrist and is placed from the radial shaft to the second or third metacarpal, depending on fracture pattern and patient anatomy. The plate provides ligamentotaxis on a temporary basis while the distal radius heals. The DVR® Crosslock Wrist Spanning Plate consists of a single, sterile-packed plate and is manufactured from titanium alloy (Ti-6AL-4V). The plate features hole clusters consisting of locking screw holes, an oblong slot, a central screw cluster, and K-wire holes for preliminary fixation. There is a dorsal bend at the distal end of the plate to accommodate patient anatomy.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The DVR® Crosslock Wrist Spanning Plate is indicated for skeletally mature patients for fixation of fractures, osteotomies and non-unions of the distal radius.

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

The subject device is only indicated for use in the distal radius, while the predicate device includes additional anatomical locations. The subject indications also identify the target population, as recommended for medical device labeling. The subject indications and inclusion of patient population do not affect safety and effectiveness of the device when used as labeled.

Technological Comparison 21 CFR 807.92(a)(6)

The subject system has the same or similar fundamental technology (indications for use, classification regulation, principles of operation, geometric shape, materials, sterility, surgical approach, and MR compatibility) as the primary predicate. The subject system has the same or similar fundamental technology (shelf-life, packaging, biological safety, and sterilization parameters) as the reference predicates. Nonclinical tests were submitted and relied on in the premarket notification submission for a determination of substantial equivalence. ASTM F382-17 (Standard Specification and Test Method for Metallic Bone Plates) testing has passed acceptance criteria established by the predicate device, where applicable. The supporting evidence in this submission concludes that the subject device is substantially equivalent to the predicate devices.

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

ASTM F382-17 Standard Specification and Test Method for Metallic Bone Plates testing was conducted in the determination of substantial equivalence. A 4-point bend test was performed via static and fatigue testing (bending structural stiffness, bending strength, and fatigue runout) to determine substantial equivalence of the subject device to the primary predicate. In addition, MR Safety analysis and testing was conducted per ASTM F2213, F2052, and F2182 to support MR Conditional labeling.

Clinical Data - Not Applicable

Static testing of the subject device (bending structural stiffness and bending strength) passed the primary predicate acceptance criteria. Fatigue testing of the subject device (fatigue runout) met the primary predicate acceptance criteria. The test results concluded that the subject device is as safe, as effective, and performs as well as the primary predicate. In addition, MR Safety analysis and testing supports MR Conditional labeling.