July 22, 2020

Pioneer Surgical Technology, Inc., DBA RTI Surgical
Sarah Pleaugh
Regulatory Affairs Manager
375 River Park Circle
Marquette, Michigan 49855

Re: K200513
Trade/Device Name: DAC Dynamic Active Compression 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, HWC
Dated: June 19, 2020
Received: June 22, 2020

Dear Sarah Pleaugh:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200513

Device Name
DAC Dynamic Active Compression Plate

Indications for Use *(Describe)*

The DAC plate system with proprietary compression technology is indicated for use in skeletally mature patients for stabilization and fixation of fractures, revisions, osteotomies, arthrodeses and reconstruction of small bones of the foot such as:

- Midfoot and hindfoot arthrodeses or osteotomies
- Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocuboid, Lapidus)
- Intercuneiform arthrodeses
- Naviculocuneiform arthrodeses
- Talonavicular arthrodeses
- Calcaneocuboid arthrodeses
- Linsfranc arthrodeses
- Mono-or-bi-cortical osteotomies in the forefoot, midfoot and hindfoot
- First metatarsophalangeal arthrodeses

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

Device Trade Name:	DAC Dynamic Active Compression Plate System
Manufacturer:	Pioneer Surgical Technology, Inc. DBA RTI Surgical, Inc. 375 River Park Circle Marquette, MI 49855 USA Registration no: 1833824 Telephone: (906) 226-9909
Contact:	Sarah Pleaugh, Manager, Regulatory Affairs Telephone: (906)226-9909 x 5861
Date Prepared:	June 19, 2020
Submission Type:	Traditional 510(k)
Common Name:	Bone Fixation Plate Bone Fixation Screw
Classification Regulation:	888.3030 – Single/multiple component metallic bone fixation appliances and accessories 888.3040 – Smooth or threaded metallic bone fixation fastener
Classification Panel:	Orthopedic
Class	II
Product Codes:	HRS, HWC

Predicate Device:

Primary Predicate: Claw® II Polyaxial Compression Plating System and Ortholoc™ 3DSi Locking Screws, K113014

Reference Device: Wright Medical FuseForce™ Staple, K124045

Purpose of Submission:

The purpose of this Traditional 510(k) is to seek clearance of a new dynamic active compression plate system for use in skeletally mature patients for stabilization and fixation of fractures, revisions, osteotomies, arthrodesis and reconstruction of small bones of the foot.

Device Description and Technological Characteristics:

The DAC Dynamic Active Compression Plate (DAC plate) System is a zero-step locking plate that provides stability and active compression. The system includes screws and plates of varying sizes and configurations to accommodate various patient anatomies. The plates contain nitinol wires housed under tension in sliders kept in place with release pins. When the built-in release pins are removed, the nitinol wires return to their straight condition, creating compression. The implant components of the system are manufactured from titanium alloy (ASTM F136) and nitinol (ASTM F2063). The components of this system should not be used with components of any other system. The implants are provided non-sterile and are supplied with instrumentation to facilitate use of the device components.

Indications for Use:

The DAC Plate System with proprietary compression technology is indicated for use in skeletally mature patients for stabilization and fixation of fractures, revisions, osteotomies, arthrodeses and reconstruction of small bones of the foot such as:

- Midfoot and hindfoot arthrodeses or osteotomies
- Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocuboid, Lapidus)
- Intercuneiform arthrodeses
- Naviculocuneiform arthrodeses
- Talonavicular arthrodeses
- Calcaneocuboid arthrodeses
- Linsfranc arthrodeses
- Mono-or-bi-cortical osteotomies in the forefoot, midfoot and hindfoot
- First metatarsophalangeal arthrodeses

Summary of Technological Characteristics

The subject system has the same intended use and technological characteristics as the predicates and the following similarities:

- Intended use: stabilization and fixation of fractures, revisions, osteotomies, arthrodesis and reconstruction of small bones of the foot
- Fundamental technology: bone plate and screw system for bone fixation
- Similar plate sizes with various configurations
- Bone Screw sizes: 2.7mm and 3.5mm diameter in 12-40mm lengths
- Packaging and sterility: sold non-sterile; steam sterilized by user
- Materials: metallic devices with well-established biological safety as orthopedic implants
- Substantially equivalent mechanical performance sufficient for the intended uses
- Instrumentation provided to aid in implantation

There are minor differences in the design characteristics of the DAC Plate System, including the nitinol wires which create compression across the fracture as the release pins are removed during surgery. This difference is design was evaluated through mechanical testing which showed equivalent performance with no new failure modes. The differences do not raise different issues of safety or effectiveness, further evidenced by all non-clinical evidence provided in this submission.

Another difference is that the subject system will be labeled as magnetic resonance (MR) conditional; performance testing has been submitted for support of this claim.

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:
    - ASTM F382-17: Standard Specification and Test Method for Metallic Bone Plates: static and dynamic 4-point bend tests
    - ASTM F543-17: Standard Specification and Test Methods for Metallic Medical Bone Screws: axial pull-out, insertion-removal torque and torsional strength tests

- ASTM F564-17: Standard Specification and Test Methods for Metallic Bone Staples: static and dynamic tension tests
- Engineering analysis of compression forces

- 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
- Cleaning and sterilization validations and evaluations
- ISO 10993-1 Biological safety evaluation
- ASTM F2129 Cyclic Potentiodynamic Polarization study for corrosion susceptibility

There are no clinical tests relied on in this premarket notification submission for a determination of substantial equivalence.

Conclusion

Based on the information provided above, the DAC Dynamic Active Compression Plate System is substantially equivalent to the predicate devices.