April 5, 2022

Orthopaedic Implant Company
Douglas Fulton
Quality Assurance Manager
770 Smithridge Dr. #400
Reno, Nevada 89502

Re: K212601
Trade/Device Name: DRPx Locking Distal Radius Plate System
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, HTN
Dated: August 13, 2021
Received: August 17, 2021

Dear Douglas Fulton:

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)*

K212601

Device Name

DRPx Locking Distal Radius Plate System

Indications for Use *(Describe)*

The DRPx Locking Distal Radius Plate System is indicated for the fixation of intra- and extra-articular fractures and osteotomies 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.

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510(k) Summary

Prepared 2/16/2022

Name and Address of Manufacturer:
The Orthopaedic Implant Company (OIC)
770 Smithridge Drive, Suite 400
Reno, NV 89502

Contact:
Douglas Fulton
Quality Assurance Manager
Telephone: 775-636-8281
Fax: 775-636-8284
Email: doug@orthoimplantcompany.com

Device Identification:
Trade Name: DRPx Locking Distal Radius Plate System
Common Name: Plate, Fixation, Bone
Classification Name: Plate, Fixation, Bone (21 CFR 888.3030)(Primary); Screw, Fixation, Bone (21 CFR 888.3040); and Washer, Bolt Nut (21 CFR 888.3030)
Classification: Class II
Panel: Orthopedic
Product Code: HRS (Primary), HWC, and HTN

Indications for Use:
The DRPx Locking Distal Radius Plate System is indicated for the fixation of intra- and extra-articular fractures and osteotomies of the distal radius.

Device Description:
The DRPx Locking Distal Radius Plate System consists of titanium plates for the distal radius, a dorsal spanning plate, bone pegs, bone screws and instruments to facilitate implantation. The Distal Radius plates come in a variety of sizes and are pre-contoured to match the anatomy of the distal radius. They accept 2.0mm locking pegs, 2.3mm locking screws, and 2.6mm and 3.5mm locking and non-locking bone screws. The bone screws range in length from 6mm to 30mm. The system also includes instruments used to implant the plates. The dorsal spanning plate is being added to the system in this submission.

Comparison of Technological Characteristics (Substantial Equivalence):
Primary predicate device: Orthopaedic Implant Company K202971 DRPx Locking Distal Radius System
Additional predicate devices: Skeletal Dynamics K150675 Dorsal Spanning Plate
K082807 Synthes (USA) 3.5mm and 4.5mm Locking Compression Plate (LCP) System with Expanded Indications
The DRPx Locking Distal Radius Plate System has the following similarities to those which previously received 510(k) concurrence:
· has the same indicated use,
· uses the same operating principle,
· incorporates a very similar design, and
· incorporates the same materials

Performance Testing:
Single cycle bend testing and bending fatigue testing were performed on the OIC Dorsal Spanning Plate and the Synthes Locking Compression Plate per ASTM F382, “Standard Specification and test Method for Metallic Bone Plates”. The plate was found to have acceptable mechanical characteristics for the intended uses.

Conclusion:
The DRPx Locking Distal Radius Plate System described in this submission is substantially equivalent to the predicate devices.