January 21, 2023

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

Re: K223118
Trade/Device Name: OIC Variable Angle Small Fragment Locking 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
Dated: December 15, 2022
Received: December 19, 2022

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,

Shumaya Ali -S

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)*
K223118

Device Name

OIC Variable Angle Small Fragment Locking Plate System

Indications for Use *(Describe)*

The OIC Variable Angle Small Fragment Locking Plate System is indicated for the fixation of fractures, mal-unions, non-unions or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, tibia, fibula, malleolus and metatarsal.

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.

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510(k) Summary - K223118

Prepared 1/16/2023

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: OIC Variable Angle Small Fragment Locking Plate System
Common Name: Plate, fixation, bone Screw, fixation, bone
Classification Name: Single/Multiple component metallic bone fixation appliances and accessories (primary), Smooth or threaded metallic bone fixation fastener
Classification: Class II, 21 CFR 888.3030 (primary), 888.3040
Panel: Orthopedic
Product Code: HRS, HWC

Indications for Use:
The OIC Variable Angle Small Fragment Locking Plate System is indicated for the fixation of fractures, fusions, mal-unions, non-unions or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, tibia, fibula, malleolus and metatarsal.

Device Description:
The OIC Variable Angle Small Fragment Locking Plate System consists of titanium plates for the Distal Radius, Clavicle, Proximal Humerus, Tibia, Distal Fibula, a Low Profile 1/3 Tubular and Hook plate, bone screws and instruments for implantation. The plates come in a variety of sizes and accept 2.5mm, 3.5mm and 4.0mm bone screws. The bone screws are available in two diameters of cortex screws (2.5mm and 3.5mm) and a 4.0mm cancellous screw. They range in length from 6mm to 130mm. The cortex screws are available with both threaded (locking) and non-threaded (non-locking) heads.

The OIC Variable Angle Small Fragment Locking Plate System is made of titanium alloy in compliance with ASTM F136, ASTM F1472 or ASTM F67.

The devices conform to the following standards:
ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws
ASTM F382, Standard Specification and Test Method for Metallic Bone Plates

The OIC Variable Angle Small Fragment Locking Plate System is provided non-sterile and is steam-sterilized by the medical facility prior to implantation.

Comparison of Technological Characteristics (Substantial Equivalence):
The predicate devices are:

Primary predicate:	OIC Variable Angle Small Fragment Locking Plate System, K140357, June 9, 2014
Secondary predicates:	Microware, Tandry Locking Plate System, K171904, Sept. 18, 2018
	Synthes (USA) 3.5mm LCP Hook Plate, K082072, Nov. 7, 2008
	Synthes (USA) TI One-Third Tubular Plate with Collar, (Pre-Amendment)

The OIC Variable Angle Small Fragment Locking 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 the same design, and
· incorporates the same or similar materials

Performance Testing:
The worst case example in terms of plate strength for plates in this filing is the 1/3 tubular plate. Single cycle bend testing was performed on the OIC Low Profile 1/3 Tubular Plate and the Synthes (USA) One-Third Tubular Plate with Collar per ASTM F382, “Standard Specification and test Method for Metallic Bone Plates”. The strength of the Hook plate was evaluated against the Microware plate using engineering analysis. The plates were found to have acceptable mechanical characteristics for the intended uses. A geometric comparison and bending strength, torsional strength and an axial pullout strength calculation was performed was performed on the 4.0mm Cancellous Screws as compared to the worst case example of screws contained in the OIC predicate - the 2.5mm Non-locking Screw. The comparison and calculations show that the system has acceptable characteristics for the intended uses.

Conclusion:
The product line extension of the OIC Variable Angle Small Fragment Locking Plate System described in this submission is substantially equivalent to the predicate devices.