October 23, 2024

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

Re: K242995
Trade/Device Name: OIC Small / Mini Fragment 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: September 25, 2024
Received: September 26, 2024

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Thomas Mcnamara -S

For: Christopher Ferreira, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242995

Device Name

OIC Small / Mini Fragment Plate System

Indications for Use *(Describe)*

The OIC Small / Mini Fragment 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.

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

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510(k) Summary

Prepared 10/21/2024

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 Small / Mini Fragment Plate System
Common Name: Plate, fixation, bone (primary), 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 (primary), HWC

Indications for Use:
The OIC Small / Mini Fragment 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.

Device Description:
The OIC Small / Mini Fragment Plate System consists of titanium plates including the Distal Radius, Clavicle, Proximal Humerus, Tibia and Distal Fibula, 1/3 tubular, Low Profile 1/3 Tubular, Hook, Olecranon and Mini Fragment, bone screws and instruments for implantation. The plates come in a variety of sizes and are pre-contoured to match the anatomy of the patient and accept 2.5mm and 3.5mm bone screws. The bone screws are available in three diameters (2.0mm, 2.5mm and 3.5mm) and range in length from 6mm to 130mm. The bone screws are available with both threaded (locking) and non-threaded (non-locking) heads.

The OIC Small / Mini Fragment 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, Standard Specification and Test Methods for Metallic Medical Bone Screws
ASTM F382, Standard Specification and Test Method for Metallic Bone Plates

The OIC Small / Mini Fragment 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, K223118
Additional predicates:	Microware, Tandry Locking Plate System, K171904
	Synthes (USA) 1.5mm Mini Fragment LCP System, K090047
	Stryker Orthopaedics, Variax Clavicle System, K113760
	Smith & Nephew, Inc., EVOS Mini-Fragment Plating System, K140814

The OIC Small / Mini Fragment 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 Mini Fragment Flat Straight plate. Single cycle bend testing was performed on the OIC plates, Microware Tandry plates and Sythes Locking Plates per ASTM F382, “Standard Specification and Test Method for Metallic Bone Plates”. The plates were found to have acceptable mechanical characteristics for the intended uses.
Torsional strength, driver torque and axial pullout strength testing were performed on the OIC 2.0mm Screws, the Microware Tandry predicate and the Synthes predicate per ASTM F543 “Standard Specification and Locking Test Methods for Metallic Medical Bone Screws”. The testing shows that the system has acceptable characteristics for the intended uses.

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