



February 2, 2024

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

Re: K233531

Trade/Device Name: OIC FLEX-FIX™ System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories

Regulatory Class: Class II

Product Code: HTN

Dated: October 30, 2023

Received: November 2, 2023

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.

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,

Limin Sun-S

Limin Sun, Ph.D.

Assistant Director

DHT6A: Division of Joint

Arthroplasty Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K233531

Device Name
OIC FLEX-FIX System

Indications for Use (Describe)

The OIC FLEX-FIX System is intended to provide fixation during the healing process following trauma to the Ankle Syndesmosis (Syndesmosis disruption) and as an adjunct in connection with trauma hardware for ankle fractures such as Weber B and C. The device is intended for use in adults.

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

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Prepared 01/29/2024

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 FLEX-FIX™ System
Common Name: Screw, Fixation, Bone
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulation Number: 21 CFR 888.3030
Classification: Class II
Panel: Orthopedic
Product Code: HTN

Indications for Use:
The OIC FLEX-FIX™ System is intended to provide fixation during the healing process following trauma to the Ankle Syndesmosis (Syndesmosis disruption) and as an adjunct in connection with trauma hardware for ankle fractures such as Weber B and C. The device is intended for use in adults.

Device Description:
The OIC FLEX-FIX™ System consists of a medial toggle body, UHMWPE suture tape and a lateral button assembled on a deployment handle, a 3.7mm drill bit, and a 3.5mm washer. The device is provided sterile. EO gas is used to sterilize the device.

The medial toggle body, lateral button and washer are manufactured from material that conforms to:
ASTM F136, Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

Comparison of Technological Characteristics (Substantial Equivalence):
The primary predicate device: Smith & Nephew, Inc K162996 INVISIKNOT Ankle Syndesmosis Repair Kit
Additional predicate devices: Biomet Orthopedics, LLC. K130033 ToggleLoc System (ZipTight Ankle Fixation)
Orthopaedic Implant Company K202971 DRPx Locking Distal Radius Plate System

The OIC FLEX-FIX™ 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
- the additional predicate devices incorporate the same materials

The following differences between the proposed device and the primary predicate were noted:

- The implants for the proposed device are made from titanium alloy while the primary predicate is stainless steel,
- The toggle body is slightly longer (10.8mm) and slightly narrower (2.85mm) than the predicate (10mm x 3.25mm)

Performance Testing:

Dynamic tensile testing and Static testing to failure was performed on the device and a predicate. The device was found to have acceptable mechanical characteristics for the intended uses.

Conclusion:

The OIC FLEX-FIX™ System described in this submission is substantially equivalent to the predicate devices.