May 5, 2021

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

Re: K211112
Trade/Device Name: OIC External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT
Dated: April 12, 2021
Received: April 14, 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,

Ting Song, Ph.D., R.A.C.
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

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)*
K211112

Device Name

OIC External Fixation System

Indications for Use *(Describe)*

The OIC External Fixation system is intended to be used in adult and pediatric patients for provisional fixation of open and/or unstable fractures in the lower and upper extremities and pelvis. It may also be used for temporary fixation of peri-articular or intra-articular fractures. Additionally, the device can be used on fractures where soft tissue injury or an infected fracture site may preclude the use of other fracture fixation treatments.

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 4/12/2021

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

Contact:
Douglas Fulton
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Device Identification:
Trade Name: OIC External Fixation System
Common Name: External fixation components
Classification Name: Single/multiple component metallic bone fixation appliances and accessories
Classification: Class II, 21 CFR 888.3030
Panel: Orthopedic
Product Code: KTT

Indications for Use:
The OIC External Fixation system is intended to be used in adult and pediatric patients for provisional fixation of open and/or unstable fractures in the lower and upper extremities and pelvis. It may also be used for temporary fixation of peri-articular or intra-articular fractures. Additionally, the device can be used on fractures where soft tissue injury or an infected fracture site may preclude the use of other fracture fixation treatments.

Device Description:
The device is used for the external stabilization of bone fractures. It consists of:
Carbon fiber composite bars, 11mm diameter, 100mm to 650mm lengths
Titanium and aluminum combination clamp, 5 & 8 hole pin clamp
Aluminum straight and angled posts
Stainless steel 3mm, 4mm and 5mm pins, blunt tip and threaded 85mm through 250mm lengths, 10mm through 120mm thread lengths.
Stainless steel 5mm transfixing pin, 300mm length
Stainless steel instruments for implantation
The pins are implanted into bone and then they are connected using the clamps, rods and posts to form a rigid construct which holds the bone fragments rigidly in place. The pins are offered in various lengths and thicknesses.

Comparison of Technological Characteristics (Substantial Equivalence):
Predicate devices: K183682 OIC External Fixation System,
Secondary predicate device: K061493 Apex Pins.
The OIC External Fixation 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:
A geometric comparison was performed on the OIC External Fixation System 3mm pins as compared to the secondary predicate. The comparison shows that the system has acceptable characteristics for the intended uses. CAD modeling and analysis were performed on the 3mm pins to evaluate the MRI safety of the new pins. The analysis indicates that these devices should be labeled MR Conditional using the same recommended MRI safety labeling as the OIC predicate.

Conclusion:
The OIC External Fixation System described in this submission is substantially equivalent to the predicate devices.