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

Re: K171211
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: August 2, 2017
Received: August 3, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
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.

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)

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 8/1/2017

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

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

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Device Description:
The device is used for the external stabilization of bone fractures. It consists of:
- Carbon fiber composite bars, 11mm diameter, 100mm to 600mm lengths
- Titanium and aluminum combination clamp, 5 & 8 hole pin clamp
- Aluminum straight and angled posts
- Stainless steel 4mm and 5mm pins, blunt tip and threaded 150mm, 200mm and 250mm lengths, 15mm through 120mm thread lengths.
- Stainless steel 5mm transfixing pin, 250mm 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: K110965 Renovis T 710 Large External Fixation System
K072212 Jet-X Bar System Clamps, Bars and Posts – MR Conditional
K952730 Hoffman II External Fixation System
K061493 Apex Pins
K031428 Synthes Large External Fixation Clamps
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:
FEA simulations were conducted using testing methods outlined in ASTM F1541-02 to ascertain that the clamping ability of the OIC clamps have acceptable mechanical characteristics for the intended uses. Mechanical static axial load testing performed per ASTM F1541-02 determined that the device will withstand greater loads than the predicate device.

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