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

July 27, 2018

Re: K181184
Trade/Device Name: OIC Intramedullary Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: June 27, 2018
Received: June 28, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181184

Device Name

OIC Intramedullary Nail System

Indications for Use *(Describe)*

The OIC Intramedullary Nail System is intended for surgical management of femoral and tibial fractures including open and closed fractures, pseudarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, tumor resections, nonunions and malunions. The hip nails may be used for basilar neck, subtrochanteric and intertrochanteric fractures. The femoral nails may be used for fractures of the femur below the hip joint including ipsilateral femur fractures, fractures proximal to a total knee arthroplasty and supracondylar fractures, including those with intra-articular extension.

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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[redacted]

510(k) Summary

Prepared 05/01/2018

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

Contact
Douglas Fulton
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Device Identification
Trade Name: OIC Intramedullary Nail System
Common Name: Hip Nail, Femoral Nail, Tibial Nail
Classification Name: Rod, Fixation, Intramedullary and Accessories
Classification: Class II, 21 CFR 888.3020
Panel: Orthopedic
Product Code: HSB

Purpose of filing
This filing is being submitted to add fifteen instruments to the OIC Intramedullary Nail System. Seven of these instruments are miscellaneous instruments to aid in installing or extracting the nails. Eight of the instruments are tools that will enable the tibial nails to be inserted using the suprapatellar approach with the knee joint in a semi-extended position.

Indications for Use
The OIC Intramedullary Nail System is intended for surgical management of femoral and tibial fractures including open and closed fractures, pseudarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, tumor resections, nonunions and malunions. The hip nails may be used for basilar neck, subtrochanteric and intertrochanteric fractures. The femoral nails may be used for fractures of the femur below the hip joint including ipsilateral femur fractures, fractures proximal to a total knee arthroplasty and supracondylar fractures, including those with intra-articular extension.

Device Description
The OIC Intramedullary Nail System consists of titanium nails for the tibia and femur, nail locking bolts, lag screws and instruments for implantation. The nails come in a variety of sizes and are pre-contoured to match the anatomy of the patient and accept 5.0mm locking bolts. The locking bolts range in length from 20mm to 130mm. The lag screws are 10.5mm in diameter and range in length from 70mm to 120mm.

The intramedullary nails, bolts and screws are made of titanium alloy Ti-6Al-4V ELI.

The additional instruments being added to the OIC Intramedullary Nail System are provided in the non-sterile condition. They are made of surgical grade stainless steel or 6061-T6 Aluminum with a medical grade silicone or Radel handle.

Substantial Equivalence
Primary predicate device:
K150655 OIC Intramedullary Nail System
Additional predicate devices:
K130595 System Modification - ZNN System Tibial Nail and Stainless Steel Tibial Nail
The new device is substantially equivalent to the predicate devices in regard to intended use, materials, and function. There are no significant differences between the OIC Intramedullary Nail System and the predicate devices listed above. Any minor differences have no effect on safety and effectiveness.

The added instruments of the OIC Intramedullary Nail System were evaluated using a geometric comparison to the predicate devices. The instrument constructs were found to have acceptable mechanical characteristics for the intended uses.