



Food and Drug Administration
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July 9, 2015

Orthopaedic Implant Company
Mr. Douglas Fulton
Quality Assurance Manager
316 California Ave #701
Reno, Nevada 89509

Re: K150655

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 3, 2015
Received: June 4, 2015

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 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 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 yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K150655

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Prepared 06/22/2015

Name and Address of Manufacturer
The Orthopaedic Implant Company (OIC)
316 California Ave #701
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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

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 in compliance with ASTM F136 or with Ti6Al4V in compliance with ASTM F1472.

The implants contained in the OIC Intramedullary Nail System are provided in both the non-sterile and sterile condition. Implants provided in the sterile condition will be sterilized with gamma radiation in accordance with methods and protocols outlined in ISO 11137-1:2006.

Substantial Equivalence

Primary predicate device:

K043431 Gamma 3 Nail System

Additional predicate devices:

K101438 T2 Greater Trochanter Nail (GTN)

K112059 T2 Femoral Nail

K003018 Titan Tibial Nail

Reference device:

K131548 Synthes Trochanteric Fixation Nail - Advanced System

The new device is substantially equivalent to the predicate devices in regards 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 nails and lag screws of the OIC Intramedullary Nail System were evaluated using a geometric comparison. The nails and the nail-lag screw constructs were found to have acceptable mechanical characteristics for the intended uses.