



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JAN 12 2012

The Orthopaedic Implant Company
% Mr. Kevin Walls
Regulatory Insight, Inc.
5401 S. Cottonwood Ct.
Greenwood Village, Colorado 80121

Re: K113123

Trade/Device Name: OIC Cannulated Screw System; OIC Sliding Hip Screw (SHS) System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT, HWC
Dated: October 20th, 2011
Received: October 21th, 2011

Dear Mr. Walls:

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

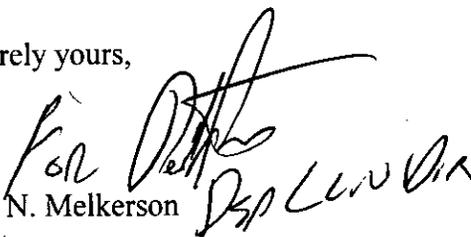
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,


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

Enclosure

Indications for Use

510(k) Number (if known): K113123

Device Name:

- a. OIC Cannulated Screw System
- b. OIC Sliding Hip Screw (SHS) System

Indications for Use:

- a. OIC Cannulated Screw System is used for adult and pediatric patients as indicated for pelvic, small and longbone fracture fixation. OIC 6.5/7.3mm cannulated screws are indicated for large bones and large bone fragments such as ankle arthrodeses, intercondylar femur fractures, pediatric femoral neck fractures (6.5mm cannulated screws only), sacroiliac joint disruptions, and subtalar arthrodeses. OIC 4.0mm cannulated screws are indicated for the fracture fixation of small bones and small bone fragments such as metatarsal and phalangeal osteotomies, fractures of the tarsals and metatarsals, tarsometatarsal and metatarsophalangeal arthrodeses, osteochondritis dissecans, and other small fragment cancellous bone fractures.
- b. The OIC Sliding Hip Screw (SHS) System is intended for use in fixation of fractures to the proximal femur. The system is indicated for use in sub-trochanteric, intertrochanteric, and basilar neck fracture. The SHS is indicated for stable fractures, and unstable fractures in which a stable medial buttress can be reconstructed. The SHS provides controlled collapse and compression of fracture fragments. This results in stable fixation and prevents undue stress concentration on the implant.

Prescription Use X AND/OR Over-The-Counter Use
 (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Wendell P. [Signature]
 (Division Sign-Off)
 Division of Surgical, Orthopedic,
 and Restorative Devices

510(k) Number K113123