K 101438

Special 510(k) Summary of Safety and Effectiveness

JUN 17 2010

Proprietary Name:	T2 Greater Trochanter Nail (GTN)
Common Name:	Intramedullary Nail, Femoral Nail
Classification Name and Reference:	Intramedullary Fixation Rod 21 CFR §888.3020
Proposed Regulatory Class:	Class II
Device Product Code:	HSB: Rod, Fixation, Intramedullary and Accessories
For Information contact:	Melissa Matarese, Regulatory Affairs Associate Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5116 Fax: (201) 831-4116
Date Prepared:	June 17, 2010

Predicate Device Identification

The T2 (Greater Trochanter Nail) is a cylindrical, cannulated titanium alloy tube, slightly bowed to accommodate the shape of the femur. The T2 GTN may be inserted into the femoral canal using either a retrograde or antegrade surgical approach.

Description of Device Modification

The predicate device is the T2 Femnoral Nail A/R which was cleared for sale under K010801 in April 2001. The intended use and indications are the same. The difference between T2 GTN and the predicate is that the nail entry point is in the grater trochater for T2 GTN, whereas for the T2 Femoral Nail A/R it is in the piriformisfossa.

Intended Use

The subject T2 GTN, like the predicate Osteo IC R/A Femoral Nail System known as the T2 Nail System, is a fracture fixation device comprised of femoral nails and the related locking screws, compression screws, and end caps. The subject and predicate devices are intended to assist with internal fracture fixation with minimal soft tissue irriation. This device is utilized as an aid to healing, not as a subsistute for normal intact bone and tissue.

Indications for Use

The subject and predicate devices are indicated for long bone fracture fixation, specifically femoral fracture fixation, which may include the following:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Ipsilateral femur fractures
- Fractures proximal to a total knee arthoplasty
- Nonunions and malunions

Statement of Substantial Equivalence:

Testing demonstrated comparable mechanical properties of the subject T2 GTN Femoral Nail System to the predicate T2 Nail in K010801. The following tests were conducted: Functionality test and influence of cannulated complression screws on the Fatigue Strength, 4-Point Bending Test, Dynamic Testing of Nail Strength, End Cap Testing, and Dynamic Fatigue Strength of T2 GTN Nails, End Product Test of fully threaded screw and shaft screw, Screw Insertion Test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.
c/o Ms. Melissa A. Matarese
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, New Jersey 07430

JUN 17 2010

Re: K101438
Trade/Device Name: T2 Greater Trochanteric Nail (GTN)
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 19, 2010
Received: May 24, 2010

Dear Ms. Matarese:

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" (21CFR 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): K 101438

Device Name: T2 GTN

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mxn

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101438