K101622 1 of 2

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

510(k) Summary

OCT 21 2010

Sponsor:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person:

Daniel J. Williman, RAC
Specialist, Regulatory Affairs
Telephone: (574) 371-8065
Fax: (574) 372-4605

Date:

September 1, 2010

Trade Name:

Zimmer® Natural Nail™ System Retrograde Femoral Nails

Common Name:

Intramedullary Fixation Rod

Classification Name and Reference:

Intramedullary fixation rod, product code HSB
21 CFR § 888.3020

Predicate Devices:

Supracondylar Intramedullary Nail, manufactured by Zimmer, Inc. (K962561, cleared September 25, 1996)

DePuy ACE Universal and Troch Entry Femoral Nail Systems, manufactured by DePuy ACE (K033329, cleared November 14, 2003)

Device Description:

The *Zimmer Natural Nail* System Retrograde Femoral Nails are a family of temporary fixation intramedullary nails designed for fracture fixation and stabilization of the femur. They are inserted into the femur in a retrograde mode and are available in a variety of lengths and diameters to meet assorted anatomical needs. Each of the intramedullary nails is secured by a series of screws that pass through holes manufactured into the proximal and distal sections of each nail. Nail caps, cortical washers and cortical nuts are available for use with the system. All components are

	manufactured from Ti-6Al-4V alloy. The cortical nut also contains UHMWPE.
Intended Use:	The *Zimmer Natural Nail* System is intended for temporary fracture fixation and stabilization of the bone. Indications for use of the retrograde femoral nails in the femur include: • Compound and simple shaft fractures • Proximal, metaphyseal, and distal shaft fractures • Segmental fractures • Closed supracondylar fractures • Severely comminuted supracondylar fractures with articular involvement • Fractures involving femoral condyles • Comminuted fractures • Fractures involving osteopenic and osteoporotic bone • Pathological fractures • Fractures with bone loss • Pseudoarthrosis, non-union, and mal-union • Periprosthetic fractures • Poly trauma patients
Comparison to Predicate Device:	The *Zimmer Natural Nail* system is similar or identical in intended use, materials, sterility, and performance characteristics to the predicate device(s).
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: The results of non-clinical (lab) performance testing demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices. Performance testing included: Proximal Nail Fatigue Test, Distal Nail Fatigue Test, Mid-shaft Nail Analysis, Nail Torsional Stiffness Analysis, Screw Bending Fatigue Test, Screw Insertion Load Test, Screw Insertion Torque Test, Screw Torque to Failure Test, and Shelf Life Testing of UHMWPE. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer Inc.
% Mr. Daniel J. Williman, RAC
Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

OCT 1 2010

Re: K101622
Trade/Device Name: Zimmer® Natural Nail™ System Retrograde Femoral Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 30, 2010
Received: October 1, 2010

Dear Mr. Williman:

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.

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,

For Mark N. Melkerson

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):

Device Name:
Zimmer® Natural Nail™ System Retrograde Femoral Nail

Indications for Use:

The *Zimmer Natural Nail* System is intended for temporary fracture fixation and stabilization of the bone.

Indications for use of the retrograde femoral nails in the femur include:

- Compound and simple shaft fractures
- Proximal, metaphyseal, and distal shaft fractures
- Segmental fractures
- Closed supracondylar fractures
- Severely comminuted supracondylar fractures with articular involvement
- Fractures involving femoral condyles
- Comminuted fractures
- Fractures involving osteopenic and osteoporotic bone
- Pathological fractures
- Fractures with bone loss
- Pseudoarthrosis, non-union, and mal-union
- Periprosthetic fractures
- Poly trauma patients

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 if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joseph C. for MKM

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

510(k) Number K101622