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zimmer

Traditional 510(k) Premarket Notification

Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708 FEB 19 2009
Contact Person:	Daniel J. Williman Associate, Regulatory Affairs Telephone: (574) 371-8065 Fax: (574) 372-4605
Date:	November 24, 2008
Trade Name:	*Zimmer*® *Natural Nail*™ System Piriformis Fossa and Greater Trochanter Antegrade Femoral Nails
Common Name:	Intramedullary Fixation Rod
Classification Name and Reference:	Intramedullary fixation rod, product code HSB 21 CFR § 888.3020
Predicate Devices:	Intramedullary Nail System, manufactured by Zimmer, Inc. (K965098, cleared February 28, 1997) *Sirus*® Nail System, manufactured by Zimmer, GmbH. (K043270, cleared January 31, 2005) DePuy ACE Universal and Troch Entry Femoral Nail Systems, manufactured by DePuy Orthopaedics (K033329, cleared November 14, 2003)
Device Description:	The *Zimmer Natural Nail* System Antegrade Femoral Nails are a family of temporary fixation intramedullary nails designed for fracture fixation and stabilization of the femur. The nails 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 are available to prevent tissue ingrowth into nail

threads and increase the length of the nail if desired. All components are available in Ti-6Al-4V alloy.

Intended Use:

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

Indications for use of the Greater Trochanter and Piriformis Fossa Antegrade Femoral nails in the femur include:

- Compound and simple shaft fractures
- Proximal, metaphyseal and distal shaft fractures
- Segmental fractures
- Comminuted fractures
- Fractures involving osteopenic and osteoporotic bone
- Pathological fractures
- Fractures with bone loss
- Pseudoarthrosis, non-union, mal-union and delayed union
- Periprosthetic fractures
- Surgically created defects such as osteotomies
- Intertrochanteric and subtrochanteric fractures

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 testing demonstrate that the devices are safe and effective.

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
9200 Corporate Boulevard
Rockville MD 20850

Zimmer, Inc.
C/o Mr. Daniel J. Williman
Regulatory Affairs Associate
P.O. Box 708
Warsaw, Indiana 46581-0708

FEB 19 2009

Re: K083497
Trade/Device Name: *Zimmer® Natural Nail™* System Piriformis Fossa and Greater Trochanter Antegrade Femoral Nails
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 24, 2008
Received: November 25, 2008

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.

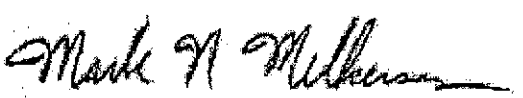
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K083497

Device Name:
Zimmer® Natural Nail™ System Piriformis Fossa and Greater Trochanter Antegrade Femoral Nails

Indications for Use:

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

Indications for use of the Greater Trochanter and Piriformis Fossa nails in the femur include:
- Compound and simple shaft fractures
- Proximal, metaphyseal and distal shaft fractures
- Segmental fractures
- Comminuted fractures
- Fractures involving osteopenic and osteoporotic bone
- Pathological fractures
- Fractures with bone loss
- Pseudoarthrosis, non-union, mal-union and delayed union
- Periprosthetic fractures
- Surgically created defects such as osteotomies
- Intertrochanteric and subtrochanteric fractures

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

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083497