

Summary of Safety and Effectiveness

JUN 30 2009

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

Contact Person: Daniel J. Williman
Associate, Regulatory Affairs
Telephone: (574) 371-8065
Fax: (574) 372-4605

Date: March 4, 2009

Trade Name: *Zimmer® Natural Nail™* System Stainless Steel
Tibial Nail & Stainless Steel 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: *Zimmer® Natural Nail™* System Tibial Nail,
manufactured by Zimmer, Inc. (K082770, cleared
December 11, 2008)

*Zimmer Natural Nail System Piriformis Fossa &
Greater Trochanter Antegrade Femoral Nails,*
manufactured by Zimmer, Inc. (K083497, cleared
February 19, 2009)

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 ACE.
(K033329, cleared November 14, 2003)

Device Description: The *Zimmer Natural Nail System* Stainless Steel
Tibial Nails are temporary fixation intramedullary
nails designed for fracture fixation and stabilization

of the tibia. The *Zimmer Natural Nail System* Stainless Steel Piriformis Fossa and Greater Trochanter Antegrade Femoral Nails are temporary fixation intramedullary nails designed for fracture fixation and stabilization of the femur. All 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 made from stainless steel.

Intended Use:

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

Indications for the Tibial nails include the following in the tibia:

- 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

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 (lab) performance 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

JUN 30 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K090596
Trade/Device Name: Zimmer Natural Nail system Stainless Steel Tibial Nail & Stainless Steel 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: June 24, 2009
Received: June 25, 2009

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.

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 (240) 276-3150 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): K090596

Device Name:

Zimmer® Natural Nail™ System Stainless Steel Tibial Nails & Stainless Steel 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 the Tibial nails include the following in the tibia:

- 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

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

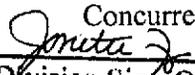
- Compound and simple shaft fractures
- Proximal, metaphyseal and distal shaft fractures
- Segmental fractures
- Comminuted fractures
- Fractures involving osteopenic and osteoporotic bone
- Pathological fractures
- Fractures with bone loss
- Pseudoarthrosis, non-union, mal-union and delayed union
-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

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 Surgical, Orthopedic,
 and Restorative Devices