



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Zimmer Inc.
Dhaval Saraiya
Regulatory Affairs Senior Specialist
345 East Main Street
Warsaw, Indiana 46580

August 10, 2017

Re: K172114
Trade/Device Name: Zimmer Natural Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: July 10, 2017
Received: July 13, 2017

Dear Mr. Saraiya:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K172114

Device Name

Zimmer Natural Nail System

Indications for Use (Describe)**ANTEGRADE FEMORAL NAILS:**

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
- Intertrchanteric and subtrochanteric fractures

RETROGRADE FEMORAL NAILS:

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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Zimmer Natural Nail (ZNN) – 6.0mm Fixed Angle Screws 510(k) premarket notification.

Sponsor: Zimmer, Inc.
345 E Main St
Warsaw, IN 46580
Establishment Registration Number: 1822565

Contact Person: Dhaval Saraiya
Regulatory Affairs Sr. Specialist
Telephone: (305-269-6386)
Fax: (305-269-6400)

Date: August 9, 2017

Subject Device: **Trade Name: Zimmer Natural Nail System**
Common Name: Intramedullary Fixation Rod

Classification Name:

- HSB– Rod, Fixation, Intramedullary and Accessories (21 CFR 888.3020)

Predicate Device(s):

K083497	Zimmer Natural Nail System Piriformis Fossa and Greater Trochanter Antegrade Femoral Nails	Zimmer Inc.
K101622	Zimmer Natural System Retrograde Femoral Nails	Zimmer Inc.

Purpose and Device Description:

The intent of this premarket notification is to provide new mechanical testing data for the Zimmer Natural Nail System – 6.0mm Fixed Angle Screws which is different than the performance specifications submitted in the original premarket notifications mentioned above. The reason for two predicate devices being identified in this submission is because these screws are used with both Zimmer Natural Nail System - Piriformis Fossa and Greater

Trochanter Antegrade Femoral Nails and Retrograde Femoral Nails and different sizes were cleared in both submissions. Since these screws are used for various nails in the same product family, we think that this still qualifies as a special 510(k) submission.

The *Zimmer Natural Nail System* is 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 the 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 made of Ti-6Al-4V alloy. The cortical nut also contains UHMWPE.

**Intended Use and
Indications for Use:**

ANTEGRADE FEMORAL NAILS:

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

RETROGRADE FEMORAL NAILS:

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

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** Same as the predicate device
- **Indications for Use:** Same as the predicate device
- **Materials:** Same as the predicate device
- **Design Features:** Same as the predicate device
- **Sterilization:** Same as the predicate device

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
 - Screw Three Point Bend Test
 - Proximal Nail Fatigue Construct Test
 - Distal Nail Fatigue Construct Test
 - Testing has been performed to establish product non-pyrogenicity
- **Clinical Tests:**
 - N/A

Substantial Equivalence Conclusion

The information provided within this premarket notification demonstrates that the Zimmer Natural Nail System Screws are substantially equivalent to the predicate devices.