K130595

P.O. Box 708
Warsaw, IN 46581-0708
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## 510(k) Summary

**Sponsor:**

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

SEP 17 2013

**Contact Person:**

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Senior Project Manager, Trauma Regulatory Affairs
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**Date:** March 5, 2013

**Trade Name:** System Modification – *ZNN* System Tibial Nail and Stainless Steel Tibial Nail

**Common Name:** Intramedullary Fixation Rod

**Classification Names and References:** Rod, Fixation, Intramedullary and Accessories (21 CFR 888.3020, Product Code HSB)

**Classification Panel:** Orthopedics/87

**Predicate Devices:** *Zimmer Natural Nail* (ZNN) System Tibial Nail (K082770, cleared December 11, 2008), *Zimmer Natural Nail* System Stainless Steel Tibial Nail (K090596, cleared June 30, 2009)

**Purpose:** This Special 510(k) is being submitted to add eight instruments to support an optional surgical technique (suprapatella approach) for the *ZNN* System Tibial Nail and *ZNN* System Stainless Steel Tibial Nail.

**Device Description:** The *ZNN* Tibial Nail System is a cannulated, intramedullary rod intended to restore the shape of the injured tibia to its pre-injured state. The nail implants are available in a variety of lengths and diameters to meet assorted anatomical needs and come in both Ti-6Al-4V alloy and 22-13-5 stainless steel to address surgeon preference. Minor modifications have been made to some of the instrumentation associated with the *ZNN* Tibial Nail System and to the surgical technique to allow implantation through an incision above the natural patella.

**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

When this device is implanted using a Suprapatella surgical approach, all of the above indications apply with the exception of Periprosthetic Fractures.

**Comparison to Predicate Device:**

The modified *ZNN* Tibial Nail System is identical to the predicate *ZNN* Tibial Nail System except that a suprapatella approach and modified instruments have been added which allow the *ZNN* Tibial Nail to be implanted through an incision above the natural patella as opposed to inserting the nail through an incision on the shelf of the tibia through or adjacent to the patellar ligament.

**Performance Data (Nonclinical and/or Clinical):**

Non-Clinical Performance and Conclusions:

The addition of an optional suprapatella technique and the associated instrumentation does not change the fundamental scientific technology of the *ZNN* Tibial Nail System. The indications for use of the modified system and the original system remain the same.

All design verification activities confirmed that the *ZNN* Tibial Nails can be implanted using the modified suprapatellar surgical technique and instruments and that they provide a safe and repeatable approach similar to the surgical technique currently used for the predicate *ZNN* Tibial Nail System. The final implanted location of the *ZNN* Tibial Nail implant is the same as with the currently cleared surgical techniques. The design verification activities concluded that all risks identified were properly mitigated.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

**Summary**

Comparisons of the design, indications, and design control activities confirmed that the modified *ZNN* Tibial Nail System is substantially equivalent to the predicate *ZNN* Tibial Nail System. The *ZNN* Tibial Nails can be implanted using the suprapatella technique and instruments and provide a safe and effective approach similar to the surgical technique currently used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 17, 2013

Zimmer Incorporated
Mr. Stephen H. McKelvey
Senior Project Manager, Trauma Regulatory Affairs
Zimmer Incorporated
P.O. Box 708
Warsaw, Indiana 46581

Re: K130595
Trade/Device Name: System Modification – ZNN System Tibial Nail and Stainless Steel Tibial Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: August 9, 2013
Received: August 14, 2013

Dear Mr. McKelvey,

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

Enclosure

# Indications for Use

**510(k) Number (if known):** K130595

**Device Name:**

System Modification – *ZNN* System Tibial Nail and Stainless Steel Tibial Nail

**Indications for Use:**

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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 if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices