DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 15, 2015

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

Re: K142281
Trade/Device Name: Zimmer M/DN Intramedullary Fixation System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: August 25, 2014
Received: August 26, 2014

Dear Mr. McKelvey:

This letter corrects our substantially equivalent letter of October 22, 2014.

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" (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 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 yours,

Lori A. Wiggins -S

for

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142281

Device Name
Zimmer M/DN Intramedullary Fixation System

Indications for Use *(Describe)*

The femoral nail is indicated for use in a variety of femoral fractures, such as:
– Subtrochanteric Fractures
– Intertrochanteric Fractures
– Comminuted Fractures
– Segmental Fractures
– Fractures with Bone Loss
– Proximal and Distal Fractures
– Nonunions

The retrograde femoral nail is indicated for use in a variety of retrograde type femoral fractures, such as:
– Closed Supracondylar Fractures
– Severely Comminuted Supracondylar Fractures with Articular Involvement
– Nonunions or Pseudoarthroses
– Malunions
– Pathological Fractures
– Fractures without Extensive Comminution
– Distal Fractures Involving Osteoporotic Bone
– Fractures Involving the Femoral Condyles that Require Open Knee Access
– T-Condylar Fractures
– Femoral Shaft Fracture with Attendant Femoral Neck Fractures (Nail to be Used in Conjunction with Fixation Screws or Plates as Needed)
– Intertrochanteric Femoral Shaft Fractures
– Ipsilateral Femorotibial Fractures (“Floating Knee” Fractures)
– Femoral Shaft Fractures
– Bilateral Femoral Shaft Fractures
– Ipsilateral Patellofemoral Fractures

The tibial nail is indicated for use in a variety of tibial fractures, such as:
– Comminuted Fractures
– Segmental Fractures
– Fractures with Bone Loss
– Proximal and Distal Fractures
– Nonunions
– Transverse Fractures
– Oblique Fractures
– Spiral Fractures
– Bilateral Fractures
– Fractures with Butterfly Fragments
– Pseudarthrosis of the Tibial Shaft
– Corrective Osteotomies

The humeral nail is indicated for use in a variety of humeral fractures, such as:
– Comminuted Fractures
– Segmental Fractures
– Fractures with Bone Loss
– Proximal and Distal Fractures
– Nonunions
– Delayed Unions
– Pathological Fractures
– Floating Elbow
– Nerve Lesion
– Multiple Trauma Injuries

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen H. McKelvey Senior Project Manager, Trauma Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 372-4605
Date:	May 4, 2015
Trade Name:	*Zimmer*® *M/DN*® Intramedullary Fixation System
Common Name:	Intramedullary Rod
Classification Name/Reference:	Rod, Intramedullary Fixation (21 CFR 888.3020, HSB)
Classification Panel:	Orthopedics/87
Predicate Device(s):	Supracondylar Intramedullary Nail (Zimmer, K962561, cleared September 25, 1996), Intramedullary Nail System (Zimmer, K965098, cleared February 28, 1997), Zimmer Natural Nail System Retrograde Femoral Nails (Zimmer, K101622, cleared October 1, 2010)
Purpose and Device Description:	This submission covers line extensions and labeling changes to the *Zimmer M/DN* Intramedullary Fixation System. The *Zimmer M/DN* Intramedullary Fixation System is used for closed nailing of femoral, tibial, and humeral shaft fractures and includes femoral nails, retrograde femoral nails, tibial nails, humeral nails, self-tapping interlocking screws, nail caps, and cortical nuts. The nails are cannulated stainless steel rods with proximal and distal holes for insertion of interlocking screws.
Intended Use:	The **femoral nail** is indicated for use in a variety of femoral fractures, such as: – Subtrochanteric Fractures – Intertrochanteric Fractures – Comminuted Fractures – Segmental Fractures

- Fractures with Bone Loss
- Proximal and Distal Fractures
- Nonunions

The **retrograde femoral nail** is indicated for use in a variety of retrograde type femoral fractures, such as:

- Closed Supracondylar Fractures
- Severely Comminuted Supracondylar Fractures with Articular Involvement
- Nonunions or Pseudoarthroses
- Malunions
- Pathological Fractures
- Fractures without Extensive Comminution
- Distal Fractures Involving Osteoporotic Bone
- Fractures Involving the Femoral Condyles that Require Open Knee Access
- T-Condylar Fractures
- Femoral Shaft Fracture with Attendant Femoral Neck Fractures (Nail to be Used in Conjunction with Fixation Screws or Plates as Needed)
- Intertrochanteric Femoral Shaft Fractures
- Ipsilateral Femorotibial Fractures ("Floating Knee" Fractures)
- Femoral Shaft Fractures
- Bilateral Femoral Shaft Fractures
- Ipsilateral Patellofemoral Fractures

The **tibial nail** is indicated for use in a variety of tibial fractures, such as:

- Comminuted Fractures
- Segmental Fractures
- Fractures with Bone Loss
- Proximal and Distal Fractures
- Nonunions
- Transverse Fractures
- Oblique Fractures
- Spiral Fractures
- Bilateral Fractures
- Fractures with Butterfly Fragments
- Pseudarthrosis of the Tibial Shaft
- Corrective Osteotomies

The **humeral nail** is indicated for use in a variety of humeral fractures, such as:

- Comminuted Fractures
- Segmental Fractures
- Fractures with Bone Loss
- Proximal and Distal Fractures
- Nonunions
- Delayed Unions
- Pathological Fractures
- Floating Elbow
- Nerve Lesion
- Multiple Trauma Injuries

Comparison to Predicate Device:

The *Zimmer M/DN* Intramedullary Fixation System nails, screws, cortical nut, and locking cap covered by this submission are similar in intended use, design, materials, and performance characteristics to the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

- **Shelf Life -** Accelerated aging testing conducted shows that the sterile nails and screws included in this submission have a shelf life of 10 years. For the cortical nut and locking cap, real time testing shows that these specific devices have a shelf life of 5 years.

- **Biocompatibility** – Biocompatibility testing on the nail and screw material was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR 58). All testing passed.

- **Performance Evaluation** – Engineering analyses were conducted for the Retrograde Femoral Nail line extensions and for the 5.5mm Cortical Nut and Nail Locking Cap to show that these devices were equivalent in strength to their respective predicate devices.

  The results demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices.

Conclusions: The data presented in this submission show that the changes do not affect the safety and/or effectiveness of the subject devices and that the subject devices will perform in a substantially equivalent manner to the predicate devices.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for these devices to show substantial equivalence.