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

May 29, 2015

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

Re: K143321
Trade/Device Name: ITST® Intertrochanteric/Subtrochanteric Fixation System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: April 27, 2015
Received: April 29, 2015

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 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,

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

Indications for Use

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

510(k) Number *(if known)*
K143321

Device Name
ITST® Intertrochanteric/Subtrochanteric Fixation System

Indications for Use *(Describe)*
The ITST Intramedullary 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

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)*

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, MA, RAC Senior Project Manager, Regulatory Affairs Telephone: 574-372-4944 Fax: (574) 372-4605
Date:	November 18, 2014
Trade Name:	*ITST*® Intertrochanteric/Subtrochanteric Fixation System
Common Name:	Rod, Fixation, Intramedullary and Accessories
Classification Names and References:	Intramedullary fixation rod (21 CFR 888.3020, HSB)
Classification Panel:	Orthopedics/87
Predicate Device(s):	*M/DN*® Intramedullary Fixation, manufactured by Zimmer (K142281, cleared October 22, 2014).
Purpose and Device Description:	The purpose of this submission is to obtain clearance for a line extension to add 4.5mm Cortical Screws to the *ITST* system. The *ITST* Intertrochanteric/ Subtrochanteric Fixation System is used for closed nailing of the femur. The system includes femoral intramedullary nails, lag strews, anti-rotation screws, cortical screws and nail caps. Cortical screws are used for distal locking of the nail.
Intended Use:	The *ITST* Intramedullary 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, and Nonunions

Comparison to Predicate Devices: Both the subject *ITST* 4.5mm and predicate *M/DN* 4.2mm devices are cortical screws with similar diameters. The subject *ITST* 4.5mm Cortical Screws have identical lengths to the predicate *M/DN* 4.2mm Cortical Screws. Both devices are made from the same material and have indications for use.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

- **Shelf Life -** Accelerated aging testing conducted shows that the sterile devices included in this submission have a shelf life of 10 years.

- **Biocompatibility** – Biocompatibility testing of the subject devices was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR 58). All testing passed.

- **Performance Evaluation** –The dimensional evaluation demonstrated that the subject *ITST* 4.5mm Cortical Screws are safe and effective and substantially equivalent to the predicate *M/DN* 4.2mm Cortical Screws.

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 *ITST* devices will perform in a substantially equivalent manner to the predicate devices.

Clinical Performance and Conclusions:

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