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Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen H. McKelvey Manager, Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 372-4605
Date:	July 31, 2003
Trade Name:	*ITST*™ Intertrochanteric Subtrochanteric Intramedullary Femoral Nail
Common Name:	Intramedullary Nail
Classification Name and Reference:	Intramedullary Fixation Rod 21 CFR § 888.3020
Predicate Device:	M/DN Intramedullary Fixation System, manufactured by Zimmer, K965098, cleared February 28, 1997.
Device Description:	The *ITST* is used to provide reduction and internal fracture fixation of the femoral head and neck and has an intramedullary nail that is curved and tapered anatomically to accommodate the curvature of the intramedullary canal.
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 • Nonunions

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Comparison to Predicate Device:	Except for modifications to facilitate easier insertion, accommodate a larger lag screw and the addition of sliding and locking nail caps, *ITST* components are identical to the predicate device. The modifications do not change the intended use or the fundamental scientific technology. The device is packaged and sterilized using the same materials and processes.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Performance testing completed as part of the design assurance procedure demonstrated that this device is safe and effective and substantially equivalent to the predicate device. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2003

Mr. Stephen H. McKelvey
Manager, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Re: K032367
Trade/Device Name: *ITST*™ Intertrochanteric Subtrochanteric Intramedullary Femoral Nail
Regulation Numbers: 21 CFR 888.3020
Regulation Names: Intramedullary fixation rod
Regulatory Class: II
Product Codes: HSB
Dated: July 31, 2003
Received: August 1, 2003

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.

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.

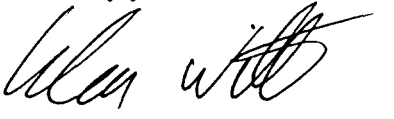
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032367

Device Name:

ITST™ Intertrochanteric Subtrochanteric Intramedullary Femoral Nail

Indications for 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
- Nonunions

(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 General, Restorative and Neurological Devices

510(k) Number K032367

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)