Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Laura D. Williams, RAC Manager, Regulatory Affairs Telephone: (574) 372-4523 Fax: (574) 372-4605
Date:	November 24, 2004
Trade Name:	*Sirus*® Intramedullary Nail
Classification Name and Reference:	Intramedullary Fixation Rod 21 CFR § 888.3020
Predicate Devices:	Unreamed Tibial Nail, manufactured by Synthes, K932330, cleared 03/08/1996 Lateral Entry Femoral Nail System by Synthes, K040336, cleared 04/12/2004 Osteo IC Retrograde/Antegrade Femoral Nail, manufactured by Osteonics, K982601, cleared 09/14/1998 T2 Femoral Nail System, manufactured by Howmedica Osteonics, K010801, K014220, and K021744; cleared 04/06/2001, 01/25/2002, and 06/26/2002, respectively
Device Description:	The *Sirus* Intramedullary Nails are manufactured from titanium alloy, and are available in a variety of lengths and diameters. They are intended for insertion into the medullary canal of the femur or tibia for the fixation of fractures.

Intended Use:

Sirus intramedullary nail for femur with cap screw and corresponding locking screws:

- All compound and simple femoral shaft fractures
- Sub-trochanteric fractures
- Pseudarthrosis and delayed union

Sirus intramedullary nail for femur in combination with the Sirus cervical screws:

- Shaft fractures in combination with femoral neck fractures or peritrochanteric fractures

Sirus intramedullary nail for tibia with cap screw and corresponding locking screws:

- Simple, compound first- and second-degree tibial shaft fractures
- Pseudarthrosis and delayed union

Comparison to Predicate Device:

The *Sirus* Intramedullary Nail has the same intended use, has similar performance characteristics, is manufactured from similar materials using similar processes, and is similar in design to the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The results of non-clinical analysis demonstrate that the device is safe and effective and substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2005

Zimmer GMBH
C/o Zimmer, Inc
Ms. Laura D. Williams, RAC
Manager, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 465810

Re: K043270
Trade/Device Name: Sirus™ Intramedullary Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: November 24, 2004
Received: November 26, 2004

Dear Ms. Williams:

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 (240) 276-0210. 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/industry/support/index.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

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Indications for Use

510(k) Number (if known):

Device Name:

Sirus™ Intramedullary Nail

Indications for Use:

Sirus intramedullary nail for femur with cap screw and corresponding locking screws

- All compound and simple femoral shaft fractures
- Sub-trochanteric fractures
- Pseudarthrosis and delayed union

Sirus intramedullary nail for femur in combination with the Sirus cervical screws

- Shaft fractures in combination with femoral neck fractures or peritrochanteric fractures

Sirus intramedullary nail for tibia with cap screw and corresponding locking screws

- Simple, compound first- and second-degree tibial shaft fractures
- Pseudarthrosis and delayed union

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)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K043270