K113409 (pg 1/2)

FEB 15 2012

510(k) Summary of Safety and Effectiveness

Proprietary Name:	S2 Nail System
Common Name:	Intramedullary Fixation Rod
Classification Name and Reference:	Intramedullary Fixation Rod 21 CFR §888.3020
Proposed Regulatory Class:	Class II
Product Codes:	87HSB: Rod, Fixation, Intramedullary and Accessory
For Information Contact:	Juma Hoshino Regulatory Affairs Associate Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5992; Fax (201)831-4992
Legally Marketed Devices to Which Substantial Equivalence Is Claimed:	K032579 – S2 Nail System K102992 – T2® Recon Nail System
Date Prepared:	November 17, 2011

Description
This Traditional 510(k) submission is being supplied to the US FDA to include targeter devices as accessories to the S2 Nail System that was cleared under K032579.

Intended Use
These devices are fracture fixation devices comprised of femoral and tibial nails and the related accessories such as locking screws, compression screws, end caps, condyle screws, and a condyle screw nut. The S2 tibial nail is intended to provide temporary stabilization of various types of fractures, malunions and nonunion of the tibia. The S2 femoral nail is intended to provide temporary stabilization of various types of fractures, malunions and nonunion of the femur.

Indications
S2 Tibial Nail
The S2 Tibial Nail is intended to provide temporary stabilization of various types of fractures, malunions and nonunion of the tibia. The nails are inserted using an opened or closed technique and can be statically, dynamically and compression locked. The S2 Tibial Nail System is indicated for long bone fracture fixation, specifically tibial fracture fixation, which may include the following:

- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Nonunion and malunion

S2 Femoral Nail

The S2 Femoral Nail is indicated for long bone fracture fixation, specifically femoral fracture fixation, which may include the following:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures and tumor resections
- Supracondylar fractures, including those with intra-articular extension
- Ipsilateral femur fractures
- Fractures proximal to a total knee arthroplasty
- Fractures distal to a hip joint
- Nonunions and malunions

Summary of Technologies

The proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate device. Inclusion of targeter devices as an accessory to the S2 Nail System does not alter the technology.

Non-Clinical Testing

A human cadaveric lab and mechanical tests were conducted. For the human cadaveric lab, the S2 nails were implanted using the targeter and other relevant components without any complications, demonstrating that products are performing as intended. In addition, bench testing conducted showed that the modifications made to the existing nail adapter does not introduce worst case scenario for product performance.

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The S2 Nail System devices are substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Howmedica Osteonics Corp.
% Ms. Juma Hoshino
325 Corporate Drive
Mahwah, New Jersey 07430

FEB 15 2012

Re: K113409
Trade/Device Name: S2 Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 17, 2011
Received: November 18, 2011

Dear Ms. Hoshino:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113409 (pg 1/1)

Device Name: S2 Nail System

S2 Tibial Nail

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- Pathologic fractures, impending pathologic fractures and tumor resections
- Supracondylar fractures, including those with intra-articular extension
- Ipsilateral femur fractures
- Fractures proximal to a total knee arthroplasty
- Fractures distal to a hip joint
- Nonunions and malunions

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113409