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APR 13 2006

Summary of Safety and Effectiveness
S2™ Recon Nail System

Proprietary Name:	S2™ Recon Nail System
Common Name:	Intramedullary Nail
Classification Name and Reference:	Intramedullary Fixation Rod 21 CFR §888.3020
Device Product Code:	87 HSB
For Information contact:	Francisco Haro, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5493 Fax: (201) 831-6038
Date Summary Prepared:	March 31, 2006

Description:

This Special 510(k) submission is intended to address a material modification and a design modification of the T2™ Recon Nail System to create the subject device, which is referred to as the S2™ Recon Nail System. The material modification involves changing the material from Titanium alloy to Stainless Steel with design changes based on the S2™ Femoral and T2™ Recon Nails. There is no change in intended use for the modified device when compared to the previously cleared device.

Intended Use:

The subject S2™ Recon Nail System, like the predicate T2™ Recon Nail System, is a fracture fixation device comprised of femoral nails and related components. The subject and predicate devices are intended to provide strong and stable internal fixation with minimal soft tissue irritation. This device is used as an aid to healing, not as a substitute for normal intact bone and tissue. The indications for use provided below are exactly the same as the T2™ Recon Nail System's indications.

Indications for Use:

The S2™ Recon Nail System indications include fixation of subtrochanteric, interochanteric, ipsilateral neck/shaft, communited proximal femoral shaft fractures, femoral fixation required as a result of pathological disease, and temporary stabilization of fractures of the femoral shaft ranging from the femoral neck to the supracondylar regions of the femur.

Substantial Equivalence:

The subject S2™ Recon Nail System shares the same intended use, and basic design concepts as that of the currently available T2™ Recon Nail System. Mechanical testing demonstrated comparable mechanical properties to the predicate components and established substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2006

Howmedica Osteonics Corporation
c/o Mr. Francisco Haro
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K060921
Trade/Device Name: S2™ Recon Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: March 31, 2006
Received: April 4, 2006

Dear Mr. Haro:

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.

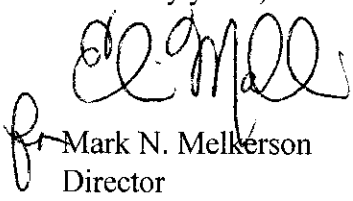
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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,



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

Enclosure

K060921

510(k) Number (if known): _____

Device Name: S2™ Recon Nail System

Indications for Use:

The S2™ Recon Nail System indications include fixation of subtrochanteric, interochanteric, ipsilateral neck/shaft, communited proximal femoral shaft fractures, femoral fixation required as a result of pathological disease, and temporary stabilization of fractures of the femoral shaft ranging from the femoral neck to the supracondylar regions of the femur.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K060921