SIGN
Surgical Implant Generation Network

SEP 23 2002

K022632
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510(k) Summary of Safety and Effectiveness

SIGN IM Nail

Contact Information

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2950 George Washington Way
Richland, WA 99352
Phone: (509) 371-1107, Fax: (509) 371-1316, e-mail: doug@sign-post.org
Date Prepared: August 1, 2002

Classification Name:	Rod, Fixation, Intramedullary and Accessories
Common Name:	Intramedullary Rod
Proprietary Name:	SIGN IM Nail
Proposed Regulatory Class:	Class II, Intramedullary Fixation Rod, 21 CFR §888.3020, OR
Device Product Code:	HSB

Substantial Equivalence Information

The SIGN IM Nail is substantially equivalent to the below listed legally marketed predicate femoral nailing devices:

1. Howmedica T2™ Femoral Nail #K010801
2. Howmedica S2™ Femoral Nail #K021026
3. Howmedica Alta® Femoral IM Rod #K972108

All of the devices listed above are similar in design, material, intended use and method of application to the SIGN IM Nail system. The safety and effectiveness of the SIGN IM Nail is also based on a long history of use of this type of device in the market place. This 510(k) serves to extend the SIGN IM Nail line, which is currently distributed under various 510(k) notifications, by adding to the indications for use and providing a greater size range.

Device Description

The SIGN IM Nail system includes Intramedullary nails, Interlocking Screws and Instruments. The SIGN IM Nail is manufactured from Solid Bar Stainless Steel, Type 316 as per ASTM F138. This device is available with diameters of 9mm, 10mm, 11mm, 12mm, 13mm and 14mm in the following lengths: 280mm, 300mm, 320mm, 340mm, 360mm, 380mm, 400mm. Each nail has holes and/or slots at both the distal and proximal ends to accept solid 4.5mm diameter cortical bone screws. Screws in a range from 25mm to 75mm in 5mm increments are supplied with the nails. Each nail uses distal and proximal bends to accommodate the shape of the femur.

Indications for use

The SIGN IM Nail is indicated for internal fixation of diaphyseal tibial fractures and distal femur fractures including transverse fractures, oblique and spiral fractures, comminuted fractures, fractures with bone loss, open fractures, corrective osteotomies, pathologic fractures, pseudoarthrosis of the tibial shaft, nonunions, malunions and fractures in the proximal femur.

The SIGN IM Nail may be removed upon fracture healing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2002

Surgical Implant Generation Network
Douglas J. Donnelly
Manager, Regulatory Affairs
2950 George Washington Way
Richland, Washington 99352-1615

Re: K022632
Trade/Device Name: SIGN IM Nail
Regulation Number: 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: August 1, 2002
Received: August 7, 2002

Dear Mr. Donnelly:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N Melkerson

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

Section VI, Indications For Use

510(k) Number (if known): K022632

Device Name: SIGN IM Nail

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K022632

(Optional Format 3-10-98)