SIGN
Creating Equality of Fracture Care Throughout the World

FEB - 3 2005

K043200

510(k) Summary of Safety and Effectiveness

SIGN Fin Nail

Contact Information

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

Substantial Equivalence Information

The SIGN Fin Nail is similar to the following Devices:
SIGN IM Nail System
Howmedica Alta IM Rod System
Biomet Brooker Femoral nail
Encore True/Flex Upper Extremity Nail

All of the devices listed above are similar in design to the SIGN Fin Nail system. The safety and effectiveness of the SIGN Fin Nail is also based on a long history of use of this type of device in the market place.

Device Description

The SIGN Fin Nail system includes intramedullary nails, Interlocking Screws and Instruments. All components are manufactured from stainless steel. The SIGN Fin Nail is available with diameters of 7mm, 8mm, 9mm, 10mm, 11mm, and 12mm in the following lengths: 160mm, 190mm, 240mm and 280mm. Each nail is made from a solid type 316, ASTM F138, solid stainless steel bar with distal and proximal bends. Each nail has a hole and a slot at the proximal end to accept solid 4.5mm diameter cortical bone screws for fixation and uses rigid distal fins for rotational stability. The SIGN Fin Nail may be removed upon fracture healing.

Indications for use

The SIGN Fin nail is indicated for internal fixation of stable fractures in the femur and humerus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 2005

Mr. Douglas J. Donnelly
Manager, Regulatory Affairs
SIGN, Inc.
2950 George Washington Way
Richland, Washington 99352

Re: K043200
Trade/Device Name: SIGN Fin Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: November 15, 2004
Received: November 18, 2004

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), please contact the Office of Compliance at (240) 276-0115. 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,

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

Indications for Use

510(k) Number (if known): K043200

Device Name: SIGN Fin Nail

Indications for Use: The SIGN Fin nail is indicated for internal fixation of stable fractures in the femur and humerus.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K043200