

JUN 22 1998

K981261

510(k) Summary

Proprietary Name:	Howmedica® SCN Nail
Common Name:	IM Rod
Classification Name & Reference:	Intramedullary Fixation Rod 21 CFR 888.3020
Proposed Regulatory Class:	II
Device Product Code:	87HSB

For information contact:	Vivian Kelly Manager, Regulatory Affairs Howmedica Inc. 359 Veterans Boulevard Rutherford, NJ 07070 Telephone: (201) 507-7830 Fax: (201) 507-6870
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The Howmedica® SCN Nail consists of supracondylar nails in various diameters and lengths, cross-locking screws, condyle screws, a condyle nut and a set screw. The nails are inserted using an opened or closed retrograde technique for the intramedullary nailing of distal femoral fractures. All of the components are fabricated from medical grade stainless steel.

The Howmedica® SCN Nail is intended to provide temporary stabilization of various types of fractures, malunions and nonunions of the distal femur including the supracondylar region. Other types of procedures include reconstruction, osteotomies, bone lengthening/shortening, prophylactic nailing of impending fractures and fusions. The condyle screw when used with the condyle nut provides good fixation in osteoporotic bone and provides compression and stabilization of the supracondylar fragments.

The substantial equivalence of this device is based on an equivalence in intended use, materials, designs and operational principles to Zimmer's Supracondylar Intramedullary Nail and Smith & Nephew Richards' Intramedullary Supracondylar Nail.



JUN 22 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John F. Dichiaro
Director of Regulatory Affairs and Public Policy
Howmedica Inc.
Pfizer Medical Technology Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K981261
Trade Name: Howmedica® SCN Nail
Regulatory Class: II
Product Code: HSB
Dated: April 6, 1998
Received: April 7, 1998

Dear Mr. Dichiaro:

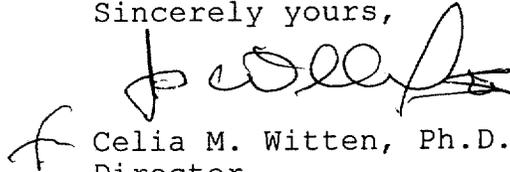
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



f Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Howmedica® SCN Nail

Indications for Use:

The Howmedica® SCN Nail is intended to provide temporary stabilization of various types of fractures, malunions and nonunions of the distal femur including the supracondylar region. Other types of procedures include reconstruction, osteotomies, bone lengthening/shortening, prophylactic nailing of impending fractures and fusions. The condyle screw when used with the condyle nut provides good fixation in osteoporotic bone and provides compression and stabilization of the supracondylar fragments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K9 81261