OCT - 6 1997

K972817

510(k) Summary

Proprietary Name:	Howmedica® Fully Threaded Screw
Common Name:	Intradmedullary 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

Howmedica's Locking Nail Systems consist of different styles of femoral, tibial and humeral nails. This line extension is to add a new type of cross-locking screw to be used with the currently marketed Grosse & Kempf® nails, Gamma® nails and Seidel™ nails cleared under various 510(k) notifications plus any future styles of stainless steel IM rods or nails. The new screw is 4.6 mm in diameter and is available in various lengths. It has a cortical buttress thread design for transverse cross-locking of IM nails. The screws are manufactured from medical grade stainless steel.

The Howmedica® Fully Threaded Screws are intended to be used for cross-locking of femoral, tibial and humeral locking nails and IM rods.

The substantial equivalence of these components is based on an equivalence in intended use, materials, design, and operational principles to Zimmer's Buttress Thread Screws and Zimmer's ZMS Recon Nail Cross-Locking Screw.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 1997

Ms. Vivian Kelly
Manager, Regulatory Affairs
Howmedica Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K972811
Trade Name: Howmedica® Fully Threaded
Cross-Locking Screws
Regulatory Class: II
Product Code: HSB
Dated: July 25, 1997
Received: July 28, 1997

Dear Ms. Kelly:

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 (Premarket 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 premarket 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,

for 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® Fully Threaded Screws

Indications for Use:

The Howmedica® Fully Threaded Screws are intended to be used for cross-locking of Howmedica's femoral, tibial and humeral locking nails and IM rods.

(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 K972811