K982068

AUG 31 1998

510(k) Summary

Proprietary Name:	Howmedica® Titanium Hoffmann® Fixation Pin System
Common Name:	External Fixation System
Classification Name & Reference:	Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040
Proposed Regulatory Class:	II
Device Product Code:	JDW OR(87)

For information contact:

Sean Luland
Regulatory Affairs Associate
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Phone: (201) 507-7437
Fax: (201) 507-6870

The Howmedica® Titanium Hoffmann® Fixation Pin System consists of half pins and transfixing pins available in a range of overall lengths, thread lengths and in shank diameters ranging from 1.5mm to 6mm. The half pins and transfixing pins are available in self-drilling and blunt tip configurations. The Howmedica® Titanium Hoffmann® Fixation Pins are designed to ease bone penetration and minimize risk of friction thermal necrosis, thereby facilitating secure bone purchase and stable fixation of the fracture.

The Howmedica® Titanium Hoffmann® Fixation Pins are inserted into the bone nearest the fracture site and connected externally to a rigid external supporting frame for immobilization of unstable fractures.

The substantial equivalence of these components is based on an equivalence in intended use, materials, design, and operational principles to the currently marketed Howmedica® Hoffmann® Fixation Pin System and the Smith & Nephew-Richards Titanium Alloy Half Pins.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 1998

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

Re: K982068
Trade Name: Howmedica® Titanium Hoffmann®
Fixation Pin System
Regulatory Class: II
Product Code: JDW
Dated: June 11, 1998
Received: June 12, 1998

Dear Mr. Dichiara:

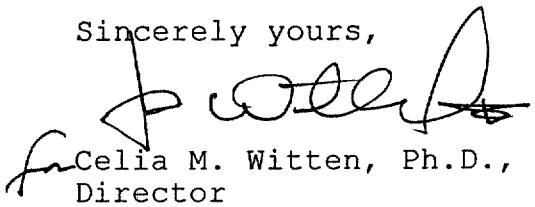
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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): K982068

Device Name: The Howmedica® Titanium Hoffmann® Fixation Pin System

Indications for Use:

The Howmedica® Titanium Hoffmann® Fixation Pin System is intended to be used in conjunction with a rigid external supporting frame for immobilization open and/or unstable fractures and where the soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting and other means of internal fixation.

(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 K982068