

NOV 25 1998

K98 34119

510(k) Summary

Proprietary Name:	Hoffmann® II Miami Post
Common Name:	External Fixation Frame Component
Classification Name & Reference:	External Fixation Device (888.3040) 21 CFR
Regulatory Class:	II
Device Product Code:	OR(87)JEC

For information contact: Joseph Volpe
Senior Regulatory Affairs Specialist
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Telephone: (201) 507-6695
Fax: (201) 507-6870

Date prepared: September 28, 1998

Intended use:

This submission describes an external fixation frame component used to connect fixator rings with 6mm mounting holes to the Hoffmann® II rod to rod and pin to rod clamps. This device is used for treating fractures, performing arthrodeses, and distraction osteogenesis of long bones, i.e., tibia, femur and humerus. It also provides stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting.

Description:

The Hoffmann® II Miami Post is designed to connect rings with 6mm holes to Hoffmann® II rod to rod and pin to rod clamps. This Post attaches the circular fixation rings to the external fixations rods. The Post is manufactured from Stainless Steel and is machined from bar stock.

Substantial Equivalence:

Equivalency of this device is based on similarities in intended use, materials, design and operational principles to the Howmedica Monticelli/Spinelli Sliding Clamp (with articulating coupling), the Synthes Ring-to-Rod Clamp and the Zimmer Torus Ring-to-Rod Clamp.

Testing of this device demonstrates substantial equivalence to another predicate ring system.



NOV 25 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: K983419
Trade Name: Hoffmann® II Miami Post
Regulatory Class: II
Product Code: HRS
Dated: September 28, 1998
Received: September 29, 1998

Dear Mr. Dichiaro:

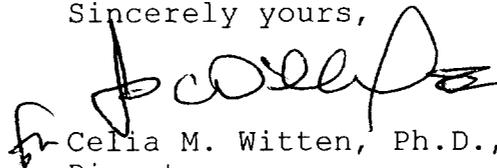
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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): Not Known

Device Name: Hoffmann® II Miami Post

Indications for Use:

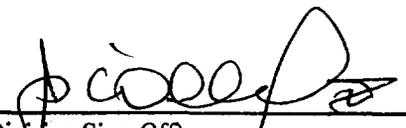
The Hoffmann® II Miami Post is used for treating fractures, performing arthrodeses, and distraction osteogenesis of long bones, i.e., tibia, femur and humerus. It also provides stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting. It is to be used to provide a hybrid construct combining any 6mm external fixation ring to the Hoffmann® II rod to rod and pin to rod clamps. The post will extend the use of the Hoffmann® II External Fixation System to Hybrid frames that utilize circular rings with 6mm mounting holes.

(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 K983419