

K97 3321

NOV 20 1997

510(k) Summary

Trade Name: Hoffmann® II Compact Periarticular Clamp
Common Name: External Fixation Device
Classification Name: Smooth or Threaded Metallic Bone Fixation Fastener
888.3040

The Periarticular Clamp is an additional component of the Hoffmann® II Compact System and is intended to be used in the stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments. It is manufactured from a lightweight plastic material which is radiographically transparent and allows for fracture or joint visibility on x-ray. The clamp can be used with the existing rods, couplings, clamps and fixation pins of the existing Hoffmann® II Compact System.

The substantial equivalence of this device is based on similarities in intended use, design and operational principles to the Original Hoffmann® Small 4-Hole Ball Joint, Hoffmann® II Compact External Fixation System and an equivalence in material and intended use to the Agee-Wristjack (Hand Biomechanics Lab, Inc) and the Radiolucent Wrist Fixation System (Orthofix).

Testing was performed to demonstrate an equivalence in performance to the Original Hoffmann® Small Four-Hole Ball Joint.

The basic operational principles for the construction of external fixation frames is similar for this new clamp to those of the named external fixation devices, that is to provide external stabilization of a fracture by means of percutaneous pins connected to a frame by means of clamps, couplings and rods. The method of site preparation, relative indications and contraindications for all the external fixation devices is similar.

For information contact: John Dichiara
Group Regulatory Affairs Manager
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
(201) 507-7386



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Dichiaro
Group Regulatory Affairs Manager
Howmedica Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

NOV 20 1997

Re: K973321
Hoffmann® II Compact Periarticular Clamp
Regulatory Class: II
Product Code: KTT
Dated: September 3, 1997
Received: September 4, 1997

Dear Mr. Dichiaro:

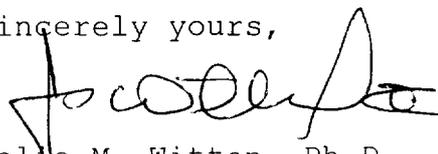
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

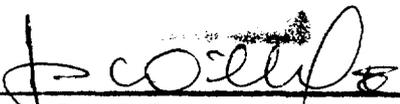
Indications for Use:

The Periarticular Clamp is intended to be used with the components of the Hoffmann® II Compact External Fixation System and the Half Pins or Transfixing Pins of the Hoffmann® External Fixation System. It is intended to be used in the stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments.

(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)



(Division Sign-Off) (Optional Format 1-2-96)
Division of General Restorative Devices
510(k) Number K973321