

K 952730

510(k) Summary

SEP-8, 1995

Device: Hoffmann® II External Fixation System

This submission describes a system of external fixation components consisting of a Pin Clamp Assembly With Post, Pin Clamp Assembly without a Fixed Post, Rod-to-Rod Coupling, Pin-to-Rod Coupling, 30° Angled Post, Straight Post, Straight Aluminum Connecting Rod and Curved Aluminum or Stainless Steel Rods. These components are intended to be used in conjunction with Half Pins or Transfixing Pins of the Hoffmann® External Fixation System (reference K861766) for the stabilization of fractures of the tibia, femur, humerus, radius or pelvis.

Testing of the components of this System is presented in this document. Evaluations included static testing of the Pin Clamp Assembly, Pin-to-Rod Coupling and Rod-to-Rod Coupling. In each test set up, the Hoffmann® II component was compared to a comparable Original Hoffmann® component.

Equivalency of this System is based on similarities in intended use, materials, design and operational principles to the Original Hoffmann® External Fixation System Components including the 5-Hole Ball Joint, 8x8 Articulating Coupling and 8x5 Articulating Coupling (Preamendment); Hoffmann® 5-Hole Lightweight Alloy Ball Joint ((K803166); Hex Fix™ External Fixation System (K841334); and Synthes External Fixator (Synthes).

All of these devices are intended to be used in an external fixation frame to stabilize bone fragments.

The Hoffmann® II External Fixation System components are manufactured from Aluminum and Stainless Steel. The Original Hoffmann® components named and the Synthes External Fixator are also manufactured from Stainless Steel. The Hoffmann® Lightweight Alloy Ball Joint is manufactured from Aluminum.

The design of each of the components of the Hoffmann® II External Fixation System, as described in this submission, are equivalent to individual components of the named equivalent products.

The basic operational principles for the construction and placement of the external fixation systems named, as well as the Hoffmann® II External Fixation System, are to provide external stabilization of a fracture by means of percutaneous pins connected to an external frame by means of Pin Clamps, Couplings and Rods. The method of site preparation and frame construction are similar for all devices named. Relative indications and contraindications for use are also the same.

For information contact: Mary C. Spicer
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP - 8 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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

Re: K952730
Trade Name: Hoffmann® II External Fixation System
Regulatory Class: II
Product Code: JEC
Dated: June 14, 1995
Received: June 15, 1995

Dear Ms. Spicer:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. 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 at (301) 443-6597.

Sincerely yours,



Kimber C. Richter, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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