

K971755

JUL 17 1997

510(k) Summary

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

This submission describes a system of external fixation components consisting of Rod-to-Rod Couplings, Pin-to-Rod Couplings, Straight and Angled Posts, a Pin Clamp Assembly, Compression/Distracton Rod-to-Rod Coupling, a Compression/Distracton Rod and Curved and Straight 5mm Rods. These components are intended to be used in conjunction with the Half Pins and Transfixing Pins of the Hoffmann® External Fixation System and may be used with the components of the Hoffmann® II External Fixation System. This device is intended to provide stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting, or other means of internal fixation.

Equivalency of this system is based on similarities in intended use, materials, design and operational principles to the Original Hoffmann® External Fixation System and the Hoffmann® II External Fixation Systems. All of these devices are intended to be used in an external fixation frame for the stabilization of bone fragments.

The Hoffmann® II Compact External Fixation Components and the Hoffmann® II External Fixation System are both manufactured from Stainless Steel and Aluminum. The Original Hoffmann® Components are manufactured from Stainless Steel.

The design of the Hoffmann® II Compact Components, the Hoffmann® II Components and the Original Hoffmann® Components are substantially equivalent.

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

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Testing of the components of this system is presented in this document. Testing compares the performance of the new components with the components of the Original Hoffmann® System or the Hoffmann II External Fixation System.

For information contact:

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Public Health Service

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Mr. John F. Dichiaro  
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JUL 17 1997

Re: K971755  
Hoffmann® II Compact External Fixation System  
Regulatory Class: II  
Product Code: JEC  
Dated: May 8, 1997  
Received: May 12, 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.

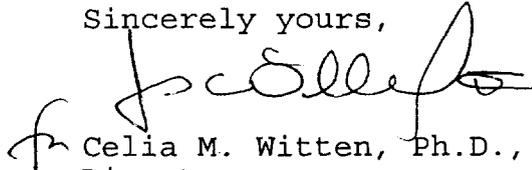
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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.  
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Enclosure

