K002923

510(k) Summary of Safety and Effectiveness for the Dynamic Joint Distractor II External Fixation System

Proprietary Name:	Dynamic Joint Distractor II External Fixation System
Common Name:	External Fixation Frame Components
Classification Name and Reference	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Regulatory Class:	Class II
Device Product Code:	87 LXT
For Information contact:	Karen Ariemma, Regulatory Affairs Specialist Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Phone: (201) 760-8187 Fax: (201) 760-8435

Intended Use:
The Dynamic Joint Distractor II External Fixation System is intended for use in patients with severe post-traumatic loss of elbow motion where protection of the articular surfaces must be obtained. This device can be used as an adjunct to surgical management of post-traumatic elbow contractures, to provide temporary stabilization and/or to help reestablish the joint space of the elbow. Surgical treatment may include soft tissue release, removal of articular adhesions and heterotropic ossification and/or fascial interposition. This device can also be used to provide temporary stabilization of the elbow joint after trauma or chronic dislocation.

Description:
The Dynamic Joint Distractor II External Fixation System has two components: the Dynamic Joint Distractor II Body and the Dynamic Joint Distractor Rod to Tube Articulation. The Dynamic Joint Distractor II Body is composed of two 5 mm diameter stainless steel rods which are linked by a hinge which includes an integrated distraction mechanism to distract the elbow joint. The Dynamic Joint Distractor II Rod to Tube Articulation allows a surgeon to connect a 5 mm diameter rod with a 15 mm diameter Compression/Distraction Hoffmann® II Compact™ Tube. The Dynamic Joint Distractor II is compatible with Hoffmann® II Compact™ Rod to Pin Clamps and Rod to Rod Clamps and either 3 mm or 4 mm diameter Apex™ Pins.

Substantial Equivalence:
Equivalency of this device is based on similarities in intended use, materials, design and operational principles to the predicate external fixation frame components. Testing of the subject components demonstrates substantial equivalence to other predicate external fixation frame components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2000

Ms. Karen Ariemma
Regulatory Affairs Specialist
Stryker Howmedica Osteonics
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K002923
Trade Name: Dynamic Joint Distractor II
Regulatory Class: II
Product Code: LXT and IQI
Dated: September 15, 2000
Received: September 19, 2000

Dear Ms. Ariemma:

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 at (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, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002923

Device Name: Dynamic Joint Distractor II External Fixation System

Indications For Use:

The Dynamic Joint Distractor II External Fixation System is intended for use in patients with severe post-traumatic loss of elbow motion where protection of the articular surfaces must be obtained. This device can be used as an adjunct to surgical management of post-traumatic elbow contractures, to provide temporary stabilization and/or to help reestablish the joint space of the elbow. Surgical treatment may include soft tissue release, removal of articular adhesions and heterotropic ossification and/or fascial interposition. This device can also be used to provide temporary stabilization of the elbow joint after trauma or chronic dislocation.

The specific indication for the use of the device that is reflected in the above circumstances is the ability to protect repaired or healing articular surfaces with a device that allows joint motion without load being imparted to the healing articular surfaces. Motion is allowed between the bones of the elbow without forces being transmitted across the bones. This is particularly helpful when an intraarticular fracture is healing or when the end of the bone has been covered with an interposition tissue to allow this tissue to heal and help avoid potential abrasion or shearing with normal joint function. Please see the draft Surgical Technique in Appendix D for a more detailed description.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002923

Prescription Use____ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)