K052498

OCT 17 2005

510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter:	David J. Slutsky M.D. South Bay Hand Surgery Center 3475 Torrance Blvd., Ste F Torrance, CA 90503
Contact person:	David J. Slutsky M.D. Phone: (310) 792-1809 FAX: (310) 792 1811
Date:	September 10, 2005
Trade Name:	Fragment Specific Fixator
Common Name:	External Fixator
Classification Name:	Smooth or threaded metallic bone fixation fastener. Single/multiple component metallic bone fixation appliances and accessories.
Classification Reference:	21 CFR 888.3040, 3030
Predicate Devices:	Millennium Medical Technologies, Inc., *Wristore* Distal Radius Fracture Fixator, K042761, cleared November 17, 2004. Howmedica Osteonics Corp., Hoffmann II Micro External Fixation System, K050048, cleared March 4, 2005.
Device Description:	The Fragment Specific Fixator is a single use external fixator designed to provide stable fracture fixation in a nonjoint bridging application that does not cross the wrist or in a joint bridging application that obtains and maintains fracture reduction through ligamentotaxis. The lightweight, radiolucent construct attaches to self drilling bone pins to provide secure fracture fixation and to capture fragments.
Intended Use:	The Fragment Specific fixator is intended for use in adult male and females from skeletal maturity to

	the geriatric population who have sustained an unstable extra-articular distal radius fracture that cannot be managed by casting, or a 3- or 4-part intra-articular fracture provided the medial fragment is large enough for the insertion of 2 separate 2.5mm - 3.0mm threaded cortical pins. The device can be used in a nonjoint bridging configuration which allows for immediate wrist motion during the fracture healing period of 6-8 weeks. It may alternatively be used in a joint bridging manner to provide ligamentotaxis to obtain and maintain the fracture reduction during the healing period.
Comparison to Predicate Device:	The Fragment Specific Fixator has the same intended use, has similar performance characteristics, is manufactured from similar materials using similar processes, and is similar in design to the predicate devices.
Performance Data:	The results of non-clinical (laboratory) performance testing demonstrate that the device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2005

David J. Slutsky, M.D.
South Bay Hand Surgery Center
3475 Torrance Boulevard, Suite F
Torrance, California 90503

Re: K052498
Trade/Device Name: Fragment Specific Fixator
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: September 10, 2005
Received: September 12, 2005

Dear Dr. Slutsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: 052498

Device Name: Fragment Specific Fixator

Indications for Use:

The Fragment Specific fixator is intended for use in adult male and females from skeletal maturity to the geriatric population who have sustained an unstable extra-articular distal radius fracture that cannot be managed by casting, or a 3- or 4-part intra-articular fracture provided the medial fragment is large enough for the insertion of 2 separate 2.5mm - 3.0mm threaded cortical pins. The device can be used in a nonjoint bridging configuration which allows for immediate wrist motion during the fracture healing period of 6-8 weeks. It may alternatively be used in a joint bridging manner to provide ligamentotaxis to obtain and maintain the fracture reduction during the healing period.

Prescription Use XXXX (Part 21 CFR 801 Subpart D) And/Or Over-the-Counter Use ___ (21 CFR 801 Subpart C)

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

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K052498