K052239

SEP 2 1 2005

510(k) SUMMARY

EBI, L.P.'s

EBI® DynaFix® Vision® FootPlate System

SUBMITTER:	EBI, L.P.
ADDRESS:	100 Interpace Parkway Parsippany, NJ 07054
PHONE:	(973) 299-9300
FAX:	(973) 257-0232
CONTACT PERSON:	Peter Allan
DATE PREPARED:	August 16, 2005
TRADE NAME:	EBI® DynaFix® Vision® FootPlate System
COMMON NAME:	External Fixation Device
CLASSIFICATION NAME:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR 888.3030
CLASSIFICATION #:	Class II
PREDICATE DEVICES:	EBI® XFIX® DFS® System, EBI® XFIX® Vision® Fixation System, Howmedica Osteonics Corporation Hoffmann® II Foot Ring

INTENDED/INDICATIONS FOR USE:

Intended for use in the treatment of bone conditions including osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by the use of the external fixation modality.

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TECHNOLOGICAL CHARACTERISTICS:

Performance Data

Mechanical testing of the FootPlate System was conducted which demonstrates that the FootPlate System conforms to its design specifications. Additionally, an Engineering Rationale was written to demonstrate that the mechanical testing conducted represented the worst-case construct and why further testing on the additional sizes of FootPlate System components is unnecessary. Mechanical testing was performed on the FootPlate System to verify the static and fatigue design specifications. In all instances, the FootPlate System functioned as intended and the test results obtained were as expected.

Substantial Equivalence

The FootPlate System is as safe and effective as the DFS and Vision Systems and has the same intended uses and similar indications, technological characteristics and principles of operation as its EBI® predicate device. The minor technological differences between the FootPlate System and its EBI® predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the FootPlate System is as safe and effective as the DFS System and Vision System. Thus, the FootPlate System is substantially equivalent. Additionally, the FootPlate System has the same intended anatomical use as the Hoffmann® II Foot Ring predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2005

Mr. Peter Allan
EBI, L.P.
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K052239
Trade/Device Name: EBI® DynaFix® Vision® FootPlate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: August 16, 2005
Received: August 17, 2005

Dear Mr. Allan:

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/dsma/dsmamain.html

Sincerely yours,

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 Statement

510(k) Number (if known):_____

Device Name: EBI® DynaFix® Vision® FootPlate System

Indications for Use:

The EBI® DynaFix® Vision® FootPlate System intended for use in the treatment of bone conditions including osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by the use of the external fixation modality.

Prescription Use X
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use____
(21 C.F.R. 807 Subpart C)

(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, and Neurological Devices

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