MAY 2 4 2006

K061098

510(k) SUMMARY

EBI, L.P.'s

EBI® OptiLock® Periarticular Plating System

SUBMITTER:	EBI, L.P.
ADDRESS:	100 Interpace Parkway Parsippany, NJ 07054
PHONE:	(973) 299-9300
FAX:	(973) 257-0232
CONTACT PERSON:	Jennifer P. Harakal
DATE PREPARED:	April 18, 2006
TRADE NAME:	EBI® OptiLock® Periarticular Plating System
COMMON NAME:	Internal Fixation Device
CLASSIFICATION NAME:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories, Smooth or threaded metallic bone fixation fastener, 21 CFR 888.3030, 21 CFR 888.3040
CLASSIFICATION #:	Class II
PREDICATE DEVICES:	EBI® Pertiarticular Plating System

INTENDED/INDICATIONS FOR USE:

The EBI® OptiLock® Periarticular Plating System (The System) is indicated for fixation of fractures and osteotomies involving the femur or tibia.

The System is intended for buttressing multifragment distal femur fractures including: supracondylar, intra-articular and extra-articular condylar fractures, fractures in normal or osteopenic bone and non-unions and malunions.

The System is intended for the treatment of non-unions, malunions and fractures of the proximal tibia, including simple, comminuted lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression and fractures with associated shaft fractures.

The System is intended to buttress Metaphyseal fractures of the medial tibial plateau, split-type fractures of the medial tibial plateau, medial split fractures with associated depressions and split of depression fractures of the medial tibia plateau. Also, for use in the fixation

of osteopenic bone and fixation of nonunions and malunions of the medial proximal tibia and tibial shaft.

The System is indicated for the fixation of fractures of the distal tibia including, but not limited to, ankle fractures, periarticular, intraarticular and distal tibia fractures with a shaft extension, malleolar and distal fibular fractures.

TECHNOLOGICAL CHARACTERISTICS:

Performance Data

Mechanical testing of the Modified System was conducted which demonstrates that the Modified System conforms to its design specifications. Additionally, Engineering Rationales were written to demonstrate why further testing on the additional sizes of the Modified System components was not required to establish substantial equivalence.

Substantial Equivalence

The Modified System is as safe and effective as its predicate devices with respect to intended use, indications for use, technological characteristics and principles of operation. The technological differences between the Modified System and its predicate devices do not raise any new issues of safety or effectiveness. Performance data and Engineering Analyses demonstrate that the Modified System is as safe and effective as its predicate devices. As such, the Modified System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2006

EBI, L.P.
% Ms. Jennifer P. Harakal
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K061098
Trade/Device Name: EBI® OptiLock® Periarticular Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: April 18, 2006
Received: April 19, 2006

Dear Ms. Harakal:

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.

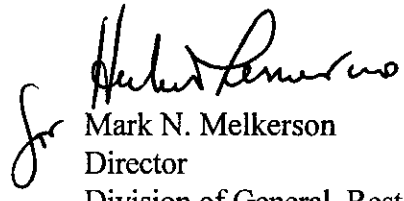
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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
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): K061098

Device Name: EBI® OptiLock® Periarticular Plating System

Indications for Use:

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Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (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

510(k) Number K061098