K062494

OCT 19 2006

510(k) Summary

This 510(k) Summary for the EBI® OptiLock Upper Extremity Plating System is provided as required per Section 513(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** EBI, L.P.

2. **Submission Prepared by:** Amy-Ahlam Chaibi
Regulatory Affairs Specialist

3. **Contact Person:**
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Parsippany, NJ 07054
Phone: (973) 299-9300, ext. 3964

Date prepared: August 18, 2006

4. **Proprietary Name:** EBI® OptiLock Upper Extremity Plating System

Common Name: Internal Fixation Device

Classification Names: Smooth or Threaded Metallic Bone Fixation Fastener, 21 CFR 888.3040
Single/Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR 888.3030

5. **Predicate or legally marketed devices that are substantially equivalent:**

- Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684)
- Synthes LCP Proximal Humerus Plate (K011815)
- Synthes LCP Proximal Humerus Plate, Long (K041860)
- Synthes 3.5 mm LCP Distal Humerus System (K033995)
- Synthes 3.5 mm Cortex Screws (K043185)

6. **Description of the device:**

The EBI **OptiLock** Upper Extremity Plating System is an internal fixation device used to provide surgeons with bone plates that are capable of using locking screws for better stability and non-locking screws for compression. Threaded slots are also available for

non-locking screws to hold the plate to the bone while adjusting the plate along the length of the bone. The shapes of the plates are pre-contoured to the shape of the bone and the holes on the plate are threaded in such a way as to permit surgeons a choice of locking or non-locking screws. Instruments allow minimum incision during surgery.

7. Intended Use:

The **OptiLock** Upper Extremity Plating System is intended for fixation of fractures and osteotomies.

The System is intended for fractures and fracture dislocations, osteotomies and non-unions of the proximal humerus, particularly in osteopenic bone.

The System is intended for fixation of fractures, osteotomies and non-unions of the olecranon, humerus, radius, ulna, particularly in osteopenic bone.

8. Materials:

The EBI® OptiLock Upper Extremity Plating System is manufactured from Stainless Steel as per ASTM F621-02, ASTM F138-03 and ASTM F139-03, and Titanium as per ASTM F136 and F620.

9. Comparison of the technological characteristics of the device to predicate devices: There are no significant differences between the EBI® OptiLock Upper Extremity Plating System and other currently marketed internal fixation systems. It is substantially equivalent* to the predicate devices in regard to intended use, materials, and function.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EBI, L.P.
% Ms. Amy Ahlam Chaibi
Regulatory Affairs Director
100 Interface Parkway
Parsippany, New Jersey 07054

OCT 19 2006

Re: K062494
Trade/Device Name: EBI® OptiLock Upper Extremity Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Pedicle screw spinal system
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: August 21, 2006
Received: August 25, 2006

Dear Ms. Chaibi:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: EBI® OptiLock Upper Extremity Plating System

Indications For Use:

The OptiLock Upper Extremity Plating System is intended for fixation of fractures and osteotomies.

The System is intended for fractures and fracture dislocations, osteotomies and non-unions of the proximal humerus, particularly in osteopenic bone.

The System is intended for fixation of fractures, osteotomies and non-unions of the olecranon, humerus, radius, ulna, particularly in osteopenic bone.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(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 k 062747