K060379

MAR 6 2006

EBI, L.P.'s

EBI® Anterior Cervical Plate 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:	February 13, 2006
TRADE NAME:	EBI® Anterior Cervical Plate System
COMMON NAME:	Spinal Fixation Device
CLASSIFICATION NAME:	Spinal Intervertebral Body Fixation Orthosis, 21 CFR § 888.3060
CLASSIFICATION #:	Class II
PREDICATE DEVICES:	EBI® VueLock® Anterior Cervical Plate System, EBI® SpineLink® Anterior Cervical Plate System, Interpore Cross International C-Tek™ Anterior Cervical Plate System, Synthes® Spine Anterior Cervical Vertabrae Plate System (Anterior CSLP)

INTENDED/INDICATIONS FOR USE:

The EBI® Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma including fractures, tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudarthroses and/or failed previous fusions.

TECHNOLOGICAL CHARACTERISTICS:

Performance Testing

Mechanical testing of the EBI® Anterior Cervical Plate System was conducted and demonstrates that the proposed system conforms to its design specifications. The design requirements were established based on those of the previously cleared predicate devices. The results of testing conducted demonstrate that the worst case of the proposed system adequately meets the requirements established in design specifications for its mechanical performance.

Substantial Equivalence

The EBI® Anterior Cervical Plate System is substantially equivalent to other legally marketed anterior cervical spinal fixation devices. Specifically, the proposed system is substantially equivalent to EBI L.P.'s VueLock® and SpineLink® Anterior Cervical Systems, Synthes' Spine Anterior Cervical Vertabrae Plate System (Anterior CSLP), and Interpore Cross International's C-Tek™ Anterior Cervical Plate System with respect to intended use and indications, technological characteristics, and principles of operation. This premarket notification is being submitted to reflect availability of a modified anterior cervical plate system that allows for the use of both constrained and semi-constrained bone screws. As demonstrated by mechanical testing, these technological differences do not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2006

EBI, LP
C/O Ms. Jennifer P. Harakal
Regulatory Affairs Specialist
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K060379
Trade/Device Name: EBI® Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 13, 2006
Received: February 14, 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.

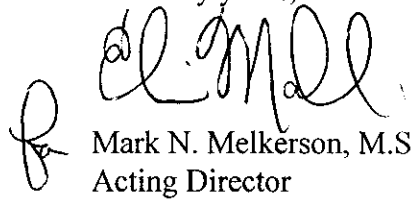
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Sincerely yours,



Mark N. Melkerson, M.S.
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): K060379

Device Name: EBI® Anterior Cervical Plate System

Indications for Use:

The EBI® Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma including fractures, tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudarthroses and/or failed previous fusions.

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)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060379