MAR 1 3 2006

K060148

510(k) SUMMARY

EBI, L.P.'s

EBI® Vertebroplasty Systems

SUBMITTER:	EBI, L.P.
ADDRESS:	100 Interpace Parkway Parsippany, NJ 07054
PHONE:	(973) 299-9300
FAX:	(973) 257-0232
CONTACT PERSON:	Debra L. Bing
DATE PREPARED:	January 16, 2006
TRADE NAME:	EBI® Vertebroplasty Systems
COMMON NAME:	Vertebral Body Cement Dispenser
CLASSIFICATION NAME:	PMMA Bone Cement, 21 CFR 888.3027
CLASSIFICATION #:	Class II
PRODUCT CODE:	LOD, NDN
PREDICATE DEVICES:	Stryker Bone Biopsy System cleared under K032943 on December 17, 2003 Abbott Spine Spinnaker System cleared under K052638 on November 7, 2005 Medtronic Sofamor Danek Equestra System cleared under K040483 on July 23, 2004

INTENDED/INDICATIONS FOR USE:

The EBI® Vertebroplasty Systems are indicated to deliver bone cement legally cleared for use in the spine for the treatment of compression fractures of a vertebral body.

TECHNOLOGICAL CHARACTERISTICS:

Performance Testing

Mechanical testing of the EBI® Vertebroplasty Systems was conducted which demonstrates that the CDO and LP^{2TM} devices conform to their design specifications. This testing demonstrated the CDO and LP^{2TM} Systems' ability to mechanically withstand insertion into a bony site and to deliver bone cement to the bony site. In all instances, the Vertebroplasty Systems functioned as intended and the test results obtained were as expected.

Substantial Equivalence

The EBI® Vertebroplasty Systems are safe and effective as the predicate devices and have the same intended uses and similar indications, technological characteristics and principles of operation as the predicate devices. The minor technological differences between the Vertebroplasty components and the predicate devices raise no new issues of safety or effectiveness. Analysis data demonstrate that the Vertebroplasty Systems, their dimensions and materials are as safe and effective as the Stryker Bone Biopsy, Abbott Spinnaker and Medtronic Sofamor Danek Equestra systems. Thus, the Vertebroplasty Systems are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2006

EBI, L.P.
c/o Ms. Debra L. Bing
Director of Regulatory Affairs
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K060148
Trade/Device Name: EBI Vertebroplasty Systems
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN
Dated: January 18, 2006
Received: January 19, 2006

Dear Ms. Bing:

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 Statement

510(k) Number (if known): K060148

Device Name: EBI® Vertebroplasty Systems

Indications for Use:

The EBI® Vertebroplasty Systems are indicated to deliver bone cement legally cleared for use in the spine for the treatment of compression fractures of a vertebral body.

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 K060148