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EBI, L.P./Biomet Spine

Solitaire™ Anterior Spinal System

OCT 17 2006

SUBMITTER:	EBI, L.P.
ADDRESS:	100 Interpace Parkway Parsippany, NJ 07054
PHONE:	(973) 299-9300
FAX:	(973) 257-0232
CONTACT PERSON:	Debra L. Bing Director, Regulatory Affairs
SUBMISSION PREPARED BY:	Jennifer P. Harakal
DATE PREPARED:	September 8, 2006
TRADE NAME:	Solitaire™ Anterior Spinal System
COMMON NAME:	Vertebral Body Replacement
CLASSIFICATION NAME:	Vertebral Body Replacement
PREDICATE DEVICE:	-Interpore Cross International Anterior Fixation Device (AFD) -Interpore Cross International Expandable PEEK VBR System -EBI ESL Spine Spacer System

INTENDED/INDICATIONS FOR USE:

The Solitaire Anterior Spinal System is indicated for use in the thoracolumbar spine (i.e., T10 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Solitaire Spine System is also indicated for treating fractures of the thoracic and lumbar spine. The Solitaire Spine System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

TECHNOLOGICAL CHARACTERISTICS:

Performance Testing

Performance data comparatively evaluating the modified system to its predicate devices demonstrate that the proposed system adequately meets the requirements established in design specifications for its mechanical performance. The design requirements were established based on those of the previously cleared predicate devices.

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Substantial Equivalence

The Solitaire Anterior Spinal System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and basic principles of operation. This premarket notification is being submitted to address a design modification, as well as to reflect additional components to the existing system. As demonstrated by performance data, 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

EBI, LP
% Ms. Debra Bing
Director, Regulatory Affairs
100 Interpace parkway
Parsippany, New Jersey 07054

OCT 17 2006

Re: K062810
Trade/Device Name: Solitaire™ Anterior Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Fixation Device
Regulatory Class: Class II
Product Code: MQP
Dated: September 15, 2006
Received: September 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.

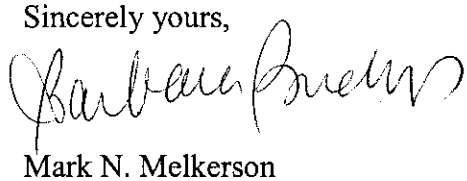
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, and Parts 800 to 898. In addition, FDA may publish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

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Indications for Use Statement

510(k) Number (if known):_____

Device Name: Solitaire™ Anterior Spinal System

Indications for Use:

The Solitaire Anterior Spinal System is indicated for use in the thoracolumbar spine (i.e., T10 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Solitaire System is also indicated for treating fractures of the thoracic and lumbar spine. The Solitaire System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

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)

K062810 Courtney Buell MD

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

510(k) Number K062810