

K062685

**EBI, L.P./Biomet Spine  
Array® Spinal System**

OC1 - 6 2006

**SUBMITTER:** EBI, L.P.  
100 Interpace Parkway  
Parsippany, NJ 07054

**SUBMISSION PREPARED BY:** Jennifer P. Harakal  
Regulatory Affairs Specialist

**CONTACT PERSON:** Debra Bing  
Regulatory Affairs Director  
Phone: 973-299-9300 x3964  
Fax: 973-257-0232

**DATE PREPARED:** September 7, 2006

**TRADE NAME:** Array® Spinal System

**COMMON NAME:** Spinal Fixation Device

**CLASSIFICATION NAME:** Spondylolisthesis Spinal Fixation Device  
Spinal Intervertebral Body Fixation Orthosis  
Spinal Interlaminar Fixation Orthosis

**PRODUCT CODE:** NKB, MNH, MNI, KWQ, KWP

**CLASS:** Class III

**REGULATION NUMBER:** 21 CFR 888.3050, 21 CFR 888.3070,  
21 CFR 888.3060

**PREDICATE DEVICES:** EBI® Array® Spinal System (Stainless Steel), K061563  
EBI® Array® Spinal Fixation System, K033312  
(formerly referred to as 'Top Loading MAS Spinal  
Fixation System')  
EBI® Webb Morley Spine System, K941367

**INTENDED/INDICATIONS FOR USE:**

The Array® Spinal System is a non-cervical spinal fixation device intended for use as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the intended use; degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformity or curvature (i.e., scoliosis, kyphosis, and/or lordosis), tumor, stenosis, pseudarthrosis, and failed previous fusion.

## **TECHNOLOGICAL CHARACTERISTICS:**

### **Performance Testing**

Mechanical testing of the Array® Spinal System was conducted and demonstrates that the proposed line extension 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 Array® Spinal System is substantially equivalent to other legally marketed spinal fixation devices with respect to intended use and indications, technological characteristics, and basic principles of operation. This premarket notification is being submitted to address a line extension to the existing Array Spinal System. 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

EBI, L.P.  
% Ms. Debra Bing  
Regulatory Affairs Director  
100 Interpace Parkway  
Parsippany, New Jersey 07054

OCT 6 - 2006

Re: K062685

Trade/Device Name: EBI<sup>®</sup> ARRAY<sup>®</sup> Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class III  
Product Code: NKB, MNI, MNH, KWP, KWQ  
Dated: September 7, 2006  
Received: September 8, 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.

Page 2 – Ms. Debra Bing

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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

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): \_\_\_\_\_

Device Name: EBI® Array® Spinal System

Indications for Use:

The Array Spinal System is a non-cervical spinal fixation device intended for use as a pedicle screw fixation system, a posterior hook and sacral/ilic screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the intended use; degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformity or curvature (i.e., scoliosis, kyphosis, and/or lordosis), tumor, stenosis, pseudarthrosis, and failed previous fusion.

Prescription Use   X    
Use \_\_\_\_\_  
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter  
  
(21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Barbara Bruch

(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number   K042685