

510(k) Summary

EBI, L.P.'s 5.5 Helical Flange Spinal System

JUL 25 2006

SUBMITTER: EBI, L.P.

ADDRESS: 100 Interpace Parkway
Parsippany, NJ 07054

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CONTACT PERSON: Jennifer P. Harakal

DATE PREPARED: May 22, 2006

TRADE NAME: EBI® 5.5 Helical Flange Spinal System

COMMON NAME: Spinal Fixation Device

CLASSIFICATION NAMES: Spondylolisthesis Spinal Fixation Device System
Spinal Intervertebral Body Fixation Orthosis
Spinal Interlaminar Fixation Orthosis

REGULATION NUMBERS: 21 CFR 888.3050, 21 CFR 888.3070, 21 CFR 888.3060

PRODUCT CODES: NKB, MNH, MNI, KWQ, KWP

PREDICATE DEVICES: -EBI® Array Spinal Fixation System/EBI® SpineLink II Spinal
Fixation system with the VuePASS™ Portal Access Surgical
System
-EBI® Array Spinal Fixation System
-EBI® Webb Morley Spine System
-Interpore Cross International Synergy™ Spinal System
(Posterior)
-Interpore Cross International Synergy Spinal System (Anterior)
-Medtronic Sofamor Danek CD HORIZON® Spinal System

INTENDED/INDICATIONS FOR USE:

The 5.5 Helical Flange 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, pseudoarthrosis, and failed previous fusion.

The 5.5 Helical Flange Spinal System Percutaneous Instruments, when used with the 5.5 Helical Flange Spinal System cannulated screws and percutaneous rods, are indicated to provide the surgeon with a percutaneous approach for posterior spinal surgery for the following indications, regardless of 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., kyphosis, and lordosis), stenosis, pseudoarthrosis, and failed previous fusion that warrant the use of a non-cervical spinal fixation device intended for use as a pedicle screw fixation system or sacral/iliac screw fixation system. Pedicle screw fixation is limited to skeletally mature patients.

The 5.5 Helical Flange Spinal System Mini-Open Instruments, when used with the 5.5 Helical Flange Spinal System implants are indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery for the following indications, regardless of 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., kyphosis, and lordosis), tumor, stenosis, pseudoarthrosis, and failed previous fusion that warrant the use of a non-cervical spinal fixation device intended for use as a pedicle screw fixation system or sacral/iliac screw fixation system. Pedicle screw fixation is limited to skeletally mature patients.

TECHNOLOGICAL CHARACTERISTICS:

Performance Testing

Mechanical testing of the EBI® 5.5 Helical Flange Spinal 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 proposed system adequately meets the requirements established in design specifications for its mechanical performance.

Substantial Equivalence

The EBI® 5.5 Helical Flange 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.



JUL 25 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EBI, LP
% Ms. Jennifer P. Harakal
Regulatory Affairs Specialist
100 Interspace Parkway
Parsippany, New Jersey 07054

Re: K061441

Trade/Device Name: EBI® 5.5 Helical Flange Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Orthosis, Spinal pedicle fixation, for degenerative disc disease
Regulatory Class: III
Product Code: NKB, MNH, MNI, KWQ, KWP
Dated: May 22, 2006
Received: May 24, 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.

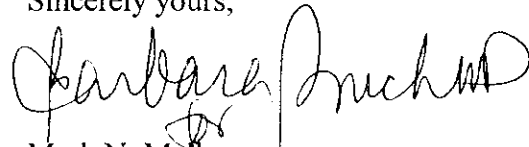
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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, stylized "M" at the end.

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® 5.5 Helical Flange Spinal System

Indications for Use:

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The 5.5 Helical Flange Spinal System Percutaneous Instruments, when used with the 5.5 Helical Flange Spinal System cannulated screws and percutaneous rods, are indicated to provide the surgeon with a percutaneous approach for posterior spinal surgery for the following indications, regardless of 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., kyphosis, and lordosis), stenosis, pseudoarthrosis, and failed previous fusion that warrant the use of a non-cervical spinal fixation device intended for use as a pedicle screw fixation system or sacral/iliac screw fixation system. Pedicle screw fixation is limited to skeletally mature patients.

The 5.5 Helical Flange Spinal System Mini-Open Instruments, when used with the 5.5 Helical Flange Spinal System implants are indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery for the following indications, regardless of 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., kyphosis, and lordosis), tumor, stenosis, pseudoarthrosis, and failed previous fusion that warrant the use of a non-cervical spinal fixation device intended for use as a pedicle screw fixation system or sacral/iliac screw fixation system. Pedicle screw fixation is limited to skeletally mature patients.

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

AND/OR

Over-The-Counter Use _____
(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)

Barbara Bonchinni for
(Division Sign-Off)

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**Division of General, Resonance
and Neurological Devices**

510(k) Number K061441