

JUL 6 2009



510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date: July 2, 2009

Applicant/Sponsor: Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Vivian Kelly
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Trade name: EBI 5.5 Helical Flange Spinal System

Common Name: Non-cervical spinal fixation system

Classification Name (Product Code): Posterior, noncervical, nonpedicle use (KWP)
Anterior/anterolateral noncervical use (KWQ)
Noncervical pedicle applications (MNI, MNH and NKB)

Device Panel - Regulation No.: Orthopedic - 21 CFR 888.3050, 888.3060 and 888.3070

Device Description:

This submission is a line extension to the EBI 5.5 Helical Flange Spinal System to add new 5.5 Polaris components, which may be used with the other 5.5mm components in order to build various types of spinal constructs. The new components include another style of screws in the larger diameters and a smaller diameter screw.

Indications for Use:

The 5.5 Helical Flange Spinal System is a non-cervical spinal fixation device intended for immobilization and stabilization as an adjunct to fusion 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 and for use with autograft. The device is indicated for all the following indications: 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 lordosis), tumor, stenosis, pseudarthrosis, and failed previous fusion.

The 5.5 Helical Flange Percutaneous Instruments are intended to be used with the 5.5 Polaris implants. The Percutaneous instruments when used with the Percutaneous cannulated screws and percutaneous rods, are indicated to provide the surgeon with a percutaneous approach for posterior spinal surgery for the following indications: 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 lordosis), tumor, stenosis, pseudarthrosis, 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 and for use with autograft.

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: 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 lordosis), tumor, stenosis, pseudarthrosis, 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/ilic screw fixation system. Pedicle screw fixation is limited to skeletally mature patients and for use with autograft.

Summary of Technologies:

The technological characteristics (material, design and sizing) of the 5.5 components are the same as, or similar to, the predicate devices.

Substantial Equivalence:

The 5.5 Helical Flange Spinal System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. Examples of predicates include EBI's Helical Flange Spinal Systems (K061441 & K041449), the Synergy Spinal System (K011437 & K081952) and the Array Spinal System (K061563). Based upon the mechanical testing, the 5.5 Helical Flange Spinal System is substantially equivalent for its intended use to other spinal systems currently on the market.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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EBI, L.P.
% Ms. Vivian Kelly
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Parsippany, New Jersey 07054

JUL 30 2009

Re: K090203

Trade/Device Name: EBI® 5.5 Helical Flange 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: July 1, 2009
Received: July 2, 2009

Dear Ms. Kelly:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson

Director

Division of Surgical, Orthopedic,
and Restorative Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

