K081636

BIOMET SPINE

510(K) Summary

AUG - 7 2008

Preparation Date:	July 30, 2008
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Vivian Kelly Phone: 973-299-9300 x2214 Fax: 973-257-0232
Trade name:	PEEK-OPTIMA® ALIF Spacer
Common Name:	Intervertebral body fusion device
Classification Name:	Intervertebral fusion device, 21 CFR §888.3080
Device Panel /Product Code:	Orthopedic MAX

Device Description:

The PEEK-OPTIMA® ALIF Spacer is a contoured device constructed of Polyetheretherketone (PEEK) medical grade, for spinal applications, inserted into the intervertebral body space of the lumbosacral spine for intervertebral body fusion.

Indications for Use:

The PEEK-OPTIMA® ALIF Spacer is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The PEEK-OPTIMA® ALIF Spacer is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Summary of Technologies:

The technological characteristics (material, design and sizing) of the PEEK-OPTIMA® ALIF Spacer are the same as, or similar to, the predicate devices.

Substantial Equivalence:

The PEEK-OPTIMA® ALIF Spacer is substantially equivalent to its predicates for intervertebral body fusion in regards to intended use, design, materials, and operational principles. Examples of other predicate intervertebral body fusion devices distributed for the similar indications include the Stryker Spine AVS PL-PEEK Spacers (K073470 and K080758) and Synthes' SynFix™-LR (K072253) while the Interpore Cross Expandable PEEK VBR Implant (K040928) has similar design features. Based upon the mechanical testing, the PEEK ALIF is substantially equivalent for its intended use to other spacers currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Spine
% Ms. Vivian Kelly
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

AUG - 7 2008

Re: K081636
Trade/Device Name: PEEK-OPTIMA® ALIF Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: June 10, 2008
Received: June 11, 2008

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Indications for Use Statement

510(k) Number (if known): K081636

Device Name: PEEK-OPTIMA® ALIF Spacer

Indications for Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 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 K081636