

K 081395



JUN 25 2008

### 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.

**Submitter:** Biomet Spine  
100 Interpace Parkway  
Parsippany, NJ 07054  
2242816

**Establishment Registration No:** 2242816

**Contact:** Vivian Kelly MS, RAC  
Regulatory Affairs Project Manager  
Biomet Spine  
100 Interpace Parkway  
Parsippany, NJ 07054  
Tel.: 973-299-9300  
Fax: 973-257-0232  
Email: Vivian.kelly@ebimed.com

**Date Prepared:** June 16, 2008

**Trade/Proprietary Name:** Solitaire™ PEEK-Optima® Anterior Spinal System

**Common/Usual Name:** Spinal device

**Classification Name and Reference:** Intervertebral body fusion device (21 CFR § 888.3080)

**Device Classification:** II

**Device Panel/Product Code:** Orthopedic (87) MAX

#### Device Description:

The Solitaire™ PEEK-Optima® Anterior Spinal System consists of a spacer with tantalum radiographic markers and bone screws for intervertebral body fusion. The spacer is PEEK with titanium inserts for the bone screw interface. The Solitaire™ Bone screws will be available in different versions of the thread types.

#### Intended Use:

The Solitaire™ PEEK-Optima® Anterior Spinal System is designed for use with autograft and is indicated for stand-alone 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.

#### Substantial Equivalence:

The Solitaire™ PEEK Optima Anterior Spinal System 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 Solitaire™ Anterior Spinal System from Interpore Cross Intl and EBI LP (K022143 & K062810) and the Interpore Cross Expandable PEEK VBR Implant (K040928) have similar design features. Based upon the mechanical testing, the Solitaire™ PEEK Optima Anterior Spinal System 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  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Biomet Spine  
% Ms. Vivian Kelly, MS, RAC  
Regulatory Affairs Project Manager  
100 Interpace Parkway  
Parsippany, NJ 07054

SEP 12 2011

Re: K081395  
Trade/Device Name: Solitaire™ PEEK-Optima® Anterior Spinal System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: OVD  
Dated: May 12, 2008  
Received: May 19, 2008

Dear Ms. Kelly:

This letter corrects our substantially equivalent letter of June 25, 2008.

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 (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 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 (301) 796-7100 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

510(k) Number (if known): K081395

Device Name: Solitaire™ PEEK-Optima® Anterior Spinal System

Indications for Use:

The Solitaire™ PEEK-Optima® Anterior Spinal System is designed for use with autograft and is indicated for stand-alone 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.

Prescription Use  X  
(Part 21 CFR 801 Subpart D)

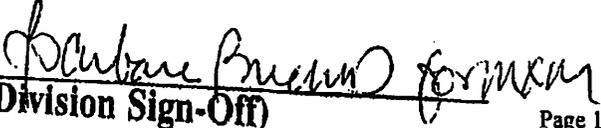
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off) Page 1 of 1

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

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