



JUN 30 2011

**510(k) Summary**

**Preparation Date:** May 9, 2011

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

**Contact Person:** Margaret F. Crowe  
Phone: 973-299-9300, ext. 2260  
Fax: 973-257-0232

**Trade name:** Zyston Curve Interbody Spacer System

**Common Name:** Non-cervical (lumbar) spinal spacer

**Classification Name:** Intervertebral body fusion device, 21 CFR §888.3080

**Device Panel/Product Code:** Orthopedic MAX

**Device Description:**

The purpose of this submission is the introduction of a new intervertebral body fusion device. The Zyston Curve Interbody Spacer System is a spacer constructed of medical grade Polyetheretherketone (PEEK) with a titanium alloy threaded insert, and tantalum radiographic markers for spinal applications.

**Indications for Use:**

The Zyston Curve Interbody Spacer System 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 Zyston Curve Interbody Spacer System 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. The Zyston Curve Interbody Spacer System may also be implanted using the Accuvision System to provide the surgeon with a minimally invasive approach for posterior or posterolateral spinal surgery.

**Summary of Technologies:**

The technological characteristics (material, design and sizing) of the Zyston Curve Spacer is the same as, or similar to, the predicate devices. Examples of predicate devices include:

- Ibex Spinal Spacer System (K091381)
- Expandable PEEK Implant (K082406)
- ESL Spacer (K092574)
- Signature™ TLIF Spacer (K072970)
- Loop™ Interbody Fusion Device (K080401)

**Performance Data**

Mechanical testing recommended in the special controls guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was conducted. The testing conducted, along with the ASTM standard, are listed below:

- 1) Static Axial Compression (ASTM F-2077)
- 2) Dynamic Axial Compression (ASTM F-2077)
- 3) Static Compression-Shear (ASTM F-2077)
- 4) Dynamic Compression-Shear (ASTM F-2077)
- 5) Subsidence (ASTM F-2267 and ASTM F-2077)

The Zyston Curve's mechanical performance met or exceeded that of the predicate device(s).

**Substantial Equivalence:**

The Zyston Curve Interbody Spacer 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. The predicates listed above are distributed for similar indications, and have similar design features.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

JUN 30 2011

Biomet Spine  
% Ms. Margaret F. Crowe  
100 Interpace Parkway  
Parsippany, New Jersey 07054

Re: K110650

Trade/Device Name: Zyston Curve Interbody Spacer System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: May 12, 2011  
Received: May 13, 2011

Dear Ms. Crowe:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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,



*SM* Mark N. Melkersón  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K110650

Device Name: Zyston Curve Interbody Spacer System

Indications for Use:

The Zyston Curve Interbody Spacer System 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 Zyston Curve Interbody Spacer System 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. The Zyston Curve Interbody Spacer System may also be implanted using the Accuvision System to provide the surgeon with a minimally invasive approach for posterior or posterolateral spinal surgery.

Prescription Use   
(Part 21 CFR 801 Subpart D)

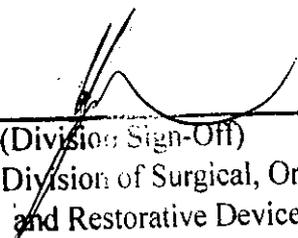
AND/OR

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

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K110650