

**BIOMET**  
ORTHOPEDICS, INC.

**510(k) Summary**

APR - 4 2007

**Preparation Date:** October 13, 2006

**Applicant/Sponsor:** Biomet Spine

**Contact Person:** Patricia Sandborn Beres  
Senior Regulatory Specialist

**Proprietary Name:** Spinal Stabilizing Sphere System

**Common Name:** Spinal Sphere

**Classification Name:** Unclassified - NVR (preamendment device)

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:** Harmon Spinal Sphere- Preamendment (Austenal Company); Fernstrom SKF Ball- Preamendment (unknown); Satellite™ Spinal System- K051320 (Medtronic Sofamor Danek)

**Device Description:** The Spinal Stabilizing Sphere System consists of two types of CoCrMo spheres (full and trimmed), which may be implanted from L3-S1 to provide temporary stabilization in order to help promote fusion.

**Intended Use:** The Spinal Stabilizing Sphere System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The Spinal Stabilizing Sphere System is intended to be used with bone graft.

**Summary of Technologies:** The technological characteristics (material, design, sizing, indications) of the Spinal Stabilizing Sphere System are similar to or identical to the predicate devices.

**Non-Clinical Testing:** Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

**Clinical Testing:** None provided as a basis for substantial equivalence.

*All trademarks are property of Biomet, Inc. except for Satellite™ (Medtronic Sofamor Danek)*

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Biomet Manufacturing Corporation  
c/o Ms. Patricia Sandborn Beres  
Senior Regulatory Specialist  
P.O. Box 587  
Warsaw, Indiana 46581-0587

APR - 4 2007

Re: K063139  
Trade/Device Name: Spinal Stabilizing Sphere System  
Regulatory Class: Unclassified  
Product Code: NVR  
Dated: March 26, 2007  
Received: March 27, 2007

Dear Ms. Sandborn Beres:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must be prominently displayed in all labeling, including pouch, box and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name:

The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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); 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 information about the application of other labeling requirements to your device (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" (21 CFR 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Miriam C. Provost*  
for Donna-Bea Tillman, Ph.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K063139

Device Name: Spinal Stabilizing Sphere System

Indications For Use:

The Spinal Stabilizing Sphere System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The Spinal Stabilizing Sphere System is intended to be used with bone graft.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use  NO   
(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)

Miriam C. Provost

(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number K063139

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