



Food and Drug Administration  
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February 28, 2017

Zimmer Biomet Spine, Inc.  
Megan Fessenden  
Regulatory Affairs, Senior Specialist  
310 Interlocken Parkway, Suite 120  
Broomfield, Colorado 80021

Re: K163543

Trade/Device Name: Biomet Fusion System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: OVD, MAX, ODP, MQP  
Dated: January 31, 2017  
Received: February 1, 2017

Dear Ms. Fessenden:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K163543

Device Name

Biomet Fusion System

Indications for Use (Describe)

When used as a cervical intervertebral body fusion device, the Biomet Intervertebral Body/VBR Fusion System (“Biomet Fusion System”) is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease (“DDD”) at one spinal level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had at least six weeks of non-operative treatment. The Biomet Cervical Intervertebral Body Fusion System is to be implanted via an anterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Biomet Anterior Cervical Plate System.

When used as a lumbar intervertebral body fusion device, the Biomet Intervertebral Body/VBR Fusion System (“Biomet Fusion System”) is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease (“DDD”) at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Implants with 14 degree lordosis or greater are only indicated from levels L2-L5 and are to be used with at least one integrated fixation screw. The Biomet Fusion System is to be combined with supplemental fixation (except as noted below). Approved supplemental fixation systems include the Biomet Spinal Fixation System. The Biomet SA standalone interbody implants, when implanted via an anterior approach and used with the integrated fixation screws, do not require use of supplement fixation.

When used as vertebral body replacement, the Biomet Intervertebral Body/VBR Fusion System (“Biomet Fusion System”) is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) The Biomet Vertebral Body Replacement System may also be used in the thoracolumbar spine (i.e. T1- L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Biomet Vertebral Body Replacement System is also indicated for treating fractures of the thoracic and lumbar spine. The Biomet Vertebral Body Replacement System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column. For either indication the system must be used with supplemental internal fixation. Supplemental internal fixation is required to properly utilize this system.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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**Biomet Spine  
Special 510(k) Premarket Notification**

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

**Preparation Date:** February 18, 2017

**Applicant/Sponsor:** Zimmer Biomet Spine Inc.  
310 Interlocken Parkway, Suite 120  
Broomfield, CO 80021

**Contact Person:** Megan Fessenden  
Regulatory Affairs, Senior Specialist  
Phone: 303.465.8994  
Fax: 303.501.8444

**Trade Name:** Biomet Fusion System

**Common Name:** Vertebral Body Replacement/Intervertebral Body Fusion Device with Integrated Fixation, Lumbar

**Device Class:** Class II

**Classification Name** Orthosis, spinal intervertebral fusion and/or Spinal intervertebral body fixation orthosis.

**Product Code:** OVD  
**Subsequent Product Codes:** MAX, MQP, ODP

**Device Panel – Regulation No.:** Orthopedic – 21 CFR 888.3080 and/or 888.3060

**Primary Predicate:** Biomet Fusion System K141791

**Device Description:**

The subject Biomet Fusion System has the same or similar intended use, indications for use, technological characteristics and principles of operation as the intervertebral body fusion devices which were reclassified as explained in FDA's guidance document, "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" (June 12, 2007). The subject Biomet Fusion is substantially equivalent to the previously cleared Biomet Fusion System (K141791).

The Biomet Fusion System is intended for use in intervertebral body fusion or vertebral body replacement. However, the implants included in this application are intended for use in lumbar intervertebral body fusion only. The subject implants are a line extension of those currently available in the Biomet Fusion System. Modifications have been made to the currently available Biomet Fusion System implants to add additional plate heights (18mm and 20mm) in both 1-hole and 2-hole configurations as well as to add a new 14-degree spacer option. As a result of these new 18mm and 20mm plates and 14 degree spacers, taller cover plates, implant trials, and implant caddies were developed to correspond to the new implant sizes.

The Biomet Fusion System implants consist of a spacer body and plates with screws for additional fixation. The spacers are made from PEEK-OPTIMA<sup>®</sup> LT1, a polyaromatic semicrystalline thermoplastic polymer (-C<sub>6</sub>H<sub>4</sub>-O-C<sub>6</sub>H<sub>4</sub>-O-C<sub>6</sub>H<sub>4</sub>-CO-), with tantalum markers. The plates and screw are made from implant grade titanium alloy (Ti-6Al-4V ELI) meeting ASTM F136-08 and ISO 5832-3. The Biomet Fusion System spacers, plates, and screws are available in a variety of sizes and configurations to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The Biomet Fusion System is provided non-sterile.

**Indications for Use:**

The indications for use of the Biomet Fusion System are as follows:

*When used as a cervical intervertebral body fusion device, the Biomet Intervertebral Body/VBR Fusion System ("Biomet Fusion System") is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one spinal level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had at least six weeks of non-operative treatment. The Biomet Cervical Intervertebral Body Fusion System is to be implanted via an anterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Biomet Anterior Cervical Plate System.*

*When used as a lumbar intervertebral body fusion device, the Biomet Intervertebral Body/VBR Fusion System ("Biomet Fusion System") is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with*

*degenerative disc disease (“DDD”) at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Implants with 14 degree lordosis or greater are only indicated from levels L2-L5 and are to be used with at least one integrated fixation screw. The Biomet Fusion System is to be combined with supplemental fixation (except as noted below). Approved supplemental fixation systems include the Biomet Spinal Fixation System. The Biomet SA standalone interbody implants, when implanted via an anterior approach and used with the integrated fixation screws, do not require use of supplement fixation.*

*When used as vertebral body replacement, the Biomet Intervertebral Body/VBR Fusion System (“Biomet Fusion System”) is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) The Biomet Vertebral Body Replacement System may also be used in the thoracolumbar spine (i.e. T1- L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Biomet Vertebral Body Replacement System is also indicated for treating fractures of the thoracic and lumbar spine. The Biomet Vertebral Body Replacement System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column. For either indication the system must be used with supplemental internal fixation. Supplemental internal fixation is required to properly utilize this system.*

### **Summary of Technological Characteristics:**

The subject Biomet Fusion System implants included in this submission have the same intended use, indications for use, technological characteristics, and principles of operation as the previously cleared Biomet Fusion System (K141791). The subject and predicate devices both include the following high-level technological characteristics:

- Lumbar intervertebral body fusion device
- Materials of construction
- Surgical procedure

The following technological characteristics are different between the subject and predicate device:

- Taller plate flange (plates)
- Taller cover plates
- Additional lordotic angle (spacers)

The minor differences in the new components do not raise any new issues of safety or effectiveness.

**Non-Clinical Testing (Risk Analysis)**

During the development of the subject Biomet Fusion System modifications a review of the Biomet Fusion System Failure Modes and Effects Analysis (FMEA) was conducted to assess and identify any new risks, including performance risks, associated with the modifications. Recommended risk mitigations described in FDA's guidance document, "*Class II Special Controls Guidance Document: Intervertebral Body Fusion Device*" (June 12, 2007), Section 6, have been implemented in accordance with this guidance document, as appropriate based on the scope of changes.

**Conclusion:**

The Biomet Spine Fusion System is substantially equivalent to the predicate systems as a spinal fusion device in regards to: intended use, indications for use, principles of operation, technological characteristics, and sterility. Furthermore, design controls and supporting information sufficiently demonstrate the substantial equivalence of the subject components to the Biomet Spine Fusion System to the predicate system. Based on this information, the subject modifications do not raise any new issues regarding the safety or efficacy when compared to its predicates.