



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Globus Medical Incorporated  
Kelly Baker, Ph.D.  
Senior Vice President, Regulatory and Clinical Affairs  
2560 General Armistead Avenue  
Audubon, Pennsylvania 19403

January 29, 2016

Re: K151939  
Trade/Device Name: COALITION® Spacers  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: OVE, ODP, KWQ  
Dated: December 29, 2015  
Received: December 30, 2015

Dear Dr. Baker:

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 Parts 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" (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 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 yours,

**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)  
K151939

K151939  
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Device Name  
COALITION® Spacers

### Indications for Use (Describe)

COALITION® Spacers (including COALITION AGX™ and COALITION MIS™) are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for one or two contiguous levels, depending on the system. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The COALITION® Spacer is a stand-alone interbody fusion device intended for use at one or two levels of the cervical spine (C2-T1) and is to be used with two titanium alloy screws which accompany the implant.

The COALITION MIS™ Spacer is an interbody fusion device and is to be used with two titanium alloy screws or anchors which accompany the implants. When used with screws, COALITION MIS™ Spacers are stand-alone interbody fusion devices intended for use at one or two levels of the cervical spine (C2-T1). When used with anchors, COALITION MIS™ Spacers are intended for use at one level of the cervical spine (C2-T1) with additional supplemental fixation such as posterior cervical screw fixation.

The COALITION AGX™ Spacer is intended to be used with supplemental fixation, such as anterior cervical plates or posterior cervical screw fixation. When used with the COALITION AGX™ Plate, the plate-spacer assembly takes on the indications for use of the COALITION AGX™ Spacer, with the COALITION AGX™ Plate acting as the supplemental fixation. The COALITION AGX™ Plate and Spacer assembly is a stand-alone device intended for use at one level of the cervical spine (C2-T1) and is to be used with two titanium alloy screws which accompany the implant.

The COALITION AGX™ Plate is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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**510(k) Summary: COALITION® Spacers**

**Company:** Globus Medical Inc.  
2560 General Armistead Ave.  
Audubon, PA 19403  
610-930-1800

**Contact:** Kelly J. Baker, Ph.D.  
Senior Vice President, Regulatory and Clinical Affairs

**Date Prepared:** January 28, 2016

**Device Name:** COALITION® Spacers

**Classification:** Per 21 CFR as follows:  
§888.3080 Intervertebral Body Fusion Device  
§888.3060 Spinal Intervertebral Body Fixation Orthosis  
Product Code(s): OVE, ODP, KWQ  
Regulatory Class: II, Panel Code: 87

**Primary Predicate:** COALITION® Spacers (K083389)

**Additional Predicates:** COALITION® Spacers (K131449)  
LDR Spine ROI-C Implant (K113559)  
Centinel Spine STALIF C (K150053)

**Purpose:**

The purpose of this submission is to request clearance for additional COALITION MIS™ implants; and to update indications for use with allogenic bone graft and at two levels for some COALITION® Spacers.

**Device Description:**

COALITION® Spacers, COALITION AGX™ Spacers, and COALITION MIS™ Spacers are cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. These spacers are inserted through an anterior cervical approach, and are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to aid in expulsion resistance. The COALITION AGX™ Plate is an anterior cervical fixation device that is available in various lengths and widths to fit the anatomical needs of a wide variety of patients. Screws are inserted through the anterior titanium portion of the implants into adjacent vertebral bodies for bony fixation. The COALITION MIS™ Spacer may also be used with anchors inserted through the anterior titanium portion of the implant into adjacent vertebral bodies.

COALITION® and COALITION MIS™ Spacers are manufactured from radiolucent PEEK polymer and titanium alloy, with titanium alloy or tantalum markers, as specified in ASTM F2026, F136, F1295, and F560. COALITION AGX™ Spacers are manufactured from radiolucent PEEK polymer, with titanium alloy or tantalum markers, as specified in ASTM F2026, F136, F1295, and F560. COALITION AGX Plates are made from titanium alloy, as specified in ASTM F136, F1295, and F1472. The COALITION MIS™ Spacer is additionally available in an all-titanium alloy version. The screws and anchors are manufactured from titanium alloy, as specified in ASTM F136 and F1295.

**Indications for Use:**

COALITION® Spacers (including COALITION AGX™ and COALITION MIS™) are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for one or two contiguous levels, depending on the system. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The COALITION® Spacer is a stand-alone interbody fusion device intended for use at one or two levels of the cervical spine (C2-T1) and is to be used with two titanium alloy screws which accompany the implant.

The COALITION MIS™ Spacer is an interbody fusion device and is to be used with two titanium alloy screws or anchors which accompany the implants. When used with screws, COALITION MIS™ Spacers are stand-alone interbody fusion devices intended for use at one or two levels of the cervical spine (C2-T1). When used with anchors, COALITION MIS™ Spacers are intended for use at one level of the cervical spine (C2-T1) with additional supplemental fixation such as posterior cervical screw fixation.

The COALITION AGX™ Spacer is intended to be used with supplemental fixation, such as anterior cervical plates or posterior cervical screw fixation. When used with the COALITION AGX™ Plate, the plate-spacer assembly takes on the indications for use of the COALITION AGX™ Spacer, with the COALITION AGX™ Plate acting as the supplemental fixation. The COALITION AGX™ Plate and Spacer assembly is a stand-alone device intended for use at one level of the cervical spine (C2-T1) and is to be used with two titanium alloy screws which accompany the implant.

The COALITION AGX™ Plate is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity

(defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

**Performance Data:**

Mechanical testing (static and dynamic compression, compression-shear, and torsion; subsidence; and expulsion) was conducted in accordance with the “Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Intervertebral Fusion Device,” June 12, 2007, ASTM F2077, and ASTM F2267. A cadaveric implantation study and biomechanical testing were performed to demonstrate substantial equivalence to the predicate spacers and to expand indications for use.

**Basis of Substantial Equivalence:**

*Comparison of Technological Characteristics and Conclusions*

COALITION MIS™ implants have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject spacers to the predicate devices. COALITION MIS™ implants are as safe, as effective, and perform as well as or better than the predicate devices.