December 20, 2017

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

Re: K173115
Trade/Device Name: COALITION® and COALITION® TPS, COALITION MIS® and COALITION MIS® TPS, COALITION AGX® and COALITION AGX® TPS
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, OVE, KWQ
Dated: September 28, 2017
Received: September 29, 2017

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 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173115

Device Name
COALITION® and COALITION® TPS,
COALITION MIS® and COALITION MIS® TPS,
COALITION AGX® and COALITION AGX® TPS

Indications for Use *(Describe)*
All COALITION® Spacers 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. Hyperlordotic implants (≥20°) must be used with supplemental fixation in addition to the two bone screws or anchors. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical and/or corticocancellous bone. All COALITION® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

The COALITION® Spacer and COALITION AGX® Plate and Spacer assembly are stand-alone integrated interbody fusion devices intended for use at one or two levels of the cervical spine (C2-T1) and used with two titanium alloy screws which accompany the implant.

The COALITION MIS® Spacer is an integrated interbody fusion device intended to be used with two titanium alloy screws and/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.

COALITION AGX® Spacer is an interbody fusion device intended to be used with supplemental fixation, such as anterior cervical plates or posterior cervical screw fixation, for one or two levels of the cervical spine (C2-T1). 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 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.

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510(k) Summary: COALITION® Additional Implants

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: December 12, 2017

Device Name: COALITION® and COALITION® TPS,
COALITION MIS® and COALITION MIS® TPS,
COALITION AGX® and COALITION AGX® TPS

Common Name: Cervical Intervertebral Body Fusion Device

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

Primary Predicate: COALITION® Spacer (K152022)

Additional Predicates: COALITION MIS® (K151939)
COALITION® TPS (K143578)
COALITION AGX® (K142218)
NuVasive CoRoent Small Interlock (K161442)
NuVasive CoRoent Small Interbody (K163491)

Purpose:
The purpose of this submission is to request clearance for additional implants and indications for the COALITION® Spacer family.

Device Description:
COALITION® Spacers (including COALITION MIS® and COALITION AGX®) are cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. COALITION® 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 MIS® Spacer may also be used with anchors inserted through the anterior titanium portion of the implant into adjacent vertebral bodies.

Indications for Use:
All COALITION® Spacers 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. Hyperlordotic implants (≥20°) must be used with supplemental fixation in addition to the two bone screws or anchors. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical and/or corticocancellous bone. All COALITION® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

The COALITION® Spacer and COALITION AGX® Plate and Spacer assembly are stand-alone integrated interbody fusion devices intended for use at one or two levels of the cervical spine (C2-T1) and used with two titanium alloy screws which accompany the implant.

The COALITION MIS® Spacer is an integrated interbody fusion device intended to be used with two titanium alloy screws and/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.

COALITION AGX® Spacer is an interbody fusion device intended to be used with supplemental fixation, such as anterior cervical plates or posterior cervical screw fixation, for one or two levels of the cervical spine (C2-T1). 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 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 compression-shear 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 to demonstrate substantial equivalence to the predicate spacers. Biomechanical

testing was performed to demonstrate equivalence to the predicate spacers and to expand indications for use.

Technological Characteristics:
COALITION® Spacers have the same technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Basis of Substantial Equivalence:
The subject COALITION® Spacer implants and additional indications 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