December 18, 2018

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

Re: K180909
Trade/Device Name: REVEL™ Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE
Dated: November 29, 2018
Received: November 30, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Katherine D. Kavlock -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*

K180909

Device Name
REVEL™ Spacers

Indications for Use *(Describe)*

REVEL™ Spacers (REVEL™ and REVEL™-S) 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 screws or anchors. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cortical, cancellous, and/or corticocancellous bone.

The REVEL™ 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.

The REVEL™-S Spacer is an integrated interbody fusion device intended to be used with two titanium alloy screws and/or anchors which accompany the implant. When used with two screws, the REVEL™-S Spacer is a stand-alone interbody fusion device intended for use at one or two levels of the cervical spine. When used with any anchors, the REVEL™-S Spacer is intended for use at one level of the cervical spine with additional supplemental fixation such as posterior cervical screw fixation.

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.

K180909
510(k) SUMMARY: REVEL™ Spacers

Company: Globus Medical Inc.
2560 General Armistead Avenue.
Audubon, PA 19403
(610) 930-1800

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

Date Prepared: November 29, 2018

Device Name: REVEL™ Spacers

Common Name: Cervical Intervertebral Body Fusion Device

Classification: Per 21 CFR as follows:
§888.3080 Intervertebral Body Fusion Device.
Product Codes: ODP, OVE
Regulatory Class: II, Panel Code: 87

Primary Predicate: Globus COALITION® Spacers (K173115)

Additional Predicates:
Spinal Elements Crystal (K153352)
Medtronic PEEK Prevail (K153373)
Globus SUSTAIN® Spacer (K130478)
Sagico IBF System Arion Cervical (K161710)

Reference Device: Globus MAGNIFY™ Spacers (K142498)

Purpose:
The purpose of this submission is to request clearance for REVEL™ Spacers.

Device Description:
REVEL™ Spacers are expandable, anterior cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The devices are available in various height expansion ranges and footprints 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 resist expulsion.

The REVEL™-S Spacer is to be used with two screws and/or anchors that are inserted through the anterior portion of the implant into adjacent vertebral bodies.

Indications for Use:
REVEL™ Spacers (REVEL™ and REVEL™-S) 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 screws or anchors. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cortical, cancellous, and/or corticocancellous bone.

The REVEL™ 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.

The REVEL™-S Spacer is an integrated interbody fusion device intended to be used with two titanium alloy screws and/or anchors which accompany the implant. When used with two screws, the REVEL™-S Spacer is a stand-alone interbody fusion device intended for use at one or two levels of the cervical spine. When used with any anchors, the REVEL™-S Spacer is intended for use at one level of the cervical spine with additional supplemental fixation such as posterior cervical screw fixation.

Technological Characteristics:
REVEL™ Spacers have the same technological characteristics as the predicate devices including the materials, design, function, range of sizes and intended use.

Performance Data:
Mechanical testing (static and dynamic compression, static and dynamic compression-shear, static and dynamic torsion, subsidence, weight loss analysis, and expulsion) for REVEL™ Spacers 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 F2025, ASTM F2077, and ASTM F2267 to demonstrate substantial equivalence to the predicate devices.

Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011. Biocompatibility of patient-contacting materials was demonstrated by using materials that meet applicable standards or are used in 510(k) cleared devices. MRI testing was assessed on the subject devices per ASTM F2052, F2119, and F2182.

Basis for Substantial Equivalence:
REVEL™ Spacers have been found to be substantially equivalent to the predicate systems with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject cervical interbody fusion devices to the predicate devices.