



Globus Medical Inc.
Lori Burns
Director, Regulatory Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

September 19, 2018

Re: K173982

Trade/Device Name: FORTIFY® Corpectomy Spacers
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP, PLR
Dated: August 20, 2018
Received: August 21, 2018

Dear Ms. Burns:

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,


Brent Showalter -S

for 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)

K173982

Device Name

FORTIFY® Corpectomy Spacers

Indications for Use (Describe)

FORTIFY® and FORTIFY® Integrated Corpectomy Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5). FORTIFY® Spacers (titanium) are also intended for use in the cervical spine (C2-T1). All FORTIFY® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

When used in the cervical spine (C2-T1), FORTIFY® devices (titanium) are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor fracture or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These spacers are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

When used in the thoracolumbar spine (T1-L5), FORTIFY® and FORTIFY® Integrated devices are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion.

These devices are intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior 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.

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510(k) Summary: FORTIFY® Additional Implants

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

Contact: Lori Burns
Director, Regulatory Affairs

Date Prepared: September 17, 2018

Device Name: FORTIFY® Corpectomy Spacers

Classification: Per 21 CFR as follows:
§888.3060 Spinal Intervertebral Fixation Orthosis
Product Code(s) : MQP, PLR
Regulatory Class II, Panel Code 87.

Primary Predicate: FORTIFY® Corpectomy Spacers (K162315)

Additional Predicates: FORTIFY® Corpectomy Spacers (K112756)
XPAND® Corpectomy Spacer (K050850)

Reference Devices: INDEPENDENCE MIS AGX (K170157)
Synthes SynMesh (K003275)
MR Compatibility (K171848)
PEEK Vendor (K152022)

Purpose:

The purpose of this submission is to request clearance for additional FORTIFY® implants consisting of variable angle endplates.

Device Description:

FORTIFY® Corpectomy Spacers are vertebral body replacement devices used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The spacers include a central core and endplates, which are available in a range of sizes and options to accommodate the anatomical needs of a wide variety of patients. The core and the endplates can be preoperatively or intraoperatively assembled to best fit individual requirements. Each spacer has an axial hole to allow autogenous bone graft or allograft comprised of cancellous or corticocancellous bone graft to be packed inside of the spacer. Protrusions (teeth) on the superior and inferior surface grips the endplate of the adjacent vertebrae to resist expulsion. FORTIFY® Variable Angle endplates provide adjustable lordosis/kyphosis.

Indications for Use:

FORTIFY® and FORTIFY® Integrated Corpectomy Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5). FORTIFY® Spacers (titanium) are also intended for use in the cervical spine (C2-T1). All FORTIFY® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

When used in the cervical spine (C2-T1), FORTIFY® devices (titanium) are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor fracture or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These spacers are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

When used in the thoracolumbar spine (T1-L5), FORTIFY® and FORTIFY® Integrated devices are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion.

These devices are intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.

Performance Data:

Mechanical testing (static and dynamic compression, static and dynamic torsion, and expulsion) was conducted in accordance with ASTM F2077 and "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004. Performance data demonstrate substantial equivalence to the predicate device. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011.

Technological Characteristics:

FORTIFY® additional implants have similar technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Basis of Substantial Equivalence:

FORTIFY® additional 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 implants to the predicate device.