December 6, 2018

Globus Medical Inc.
Kelly Baker, PhD
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K181357
Trade/Device Name: PATRIOT® Lumbar Spacers, SUSTAIN® Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, PHM
Dated: November 2, 2018
Received: November 5, 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,

Melissa Hall -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)*
K181357

Device Name
PATRIOT® Lumbar Spacers

Indications for Use *(Describe)*

PATRIOT® Spacers (including CONSTITUTION®, SIGNATURE®, CONTINENTAL®, TransContinental®, and TransContinental® M) are interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. PATRIOT® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices ($\geq 20°$ lordosis) must be used with at least anterior supplemental fixation. All PATRIOT® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

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.

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)*
K181357

Device Name
SUSTAIN® Spacers

Indications for Use *(Describe)*

When used as thoracolumbar intervertebral body fusion devices, SUSTAIN® Spacers (including SUSTAIN® R, SUSTAIN®-IR, and SUSTAIN®-RT) are indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back 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) months of non-operative treatment. SUSTAIN® Spacers are to be used with autograft and/or allogenic bone graft comprised of cancellous, and/or corticocancellous bone graft. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). All SUSTAIN® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

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.

510(k) Summary: PATRIOT® Lumbar Spacers and SUSTAIN® Spacers

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

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

Date Prepared: December 4, 2018

Device Name: PATRIOT® Lumbar Spacers
SUSTAIN® Spacers

Common Name: Intervertebral Body Fusion Device

Classification: Per 21 CFR as follows:
§888.3080 Intervertebral Body Fusion Device
Product Code(s): MAX, PHM
Regulatory Class: II, Panel Code: 87

Primary Predicate: PATRIOT® Spacers (Lumbar) (K072970)

Additional Predicates:
PATRIOT® Spacers (Lumbar) (K093242, K102313, K122097, K143578, K152022, K161223)
SUSTAIN® R Spacers (K130478, K143578, K151665, K152022)
CALIBER® Spacers (K123231)
NuVasive CoRoent Thoracolumbar System (K170962)
Stryker Spine AVS Navigation PEEK Spacer (K100865)
Medtronic CRESCENT Spinal System (K171031)

Reference Device: DePuy Synthes SYNFIX Lateral (K131276)

Purpose:
The purpose of this submission is to request clearance for additional implants and indications for the PATRIOT and SUSTAIN spacers.

Device Description:
PATRIOT® Spacers
PATRIOT® Spacers (including CONSTITUTION®, SIGNATURE®, CONTINENTAL®, TransContinental®, and TransContinental® M) are thoracolumbar interbody fusion devices used to provide structural stability in

skeletally mature individuals following discectomy. Each of the PATRIOT® spacers provides a different shape to accommodate various surgical approaches to the spine. CONSTITUTION® PLIF Spacers are inserted using a posterior or transforaminal approach. SIGNATURE® TLIF Spacers are inserted using a transforaminal or lateral approach. CONTINENTAL® ALIF Spacers are inserted using an anterior, anterolateral, or lateral approach. TransContinental® and TransContinental® M Spacers are inserted using an anterior, anterolateral, or lateral approach. All approaches may be used in the lumbar spine; only anterior, anterolateral, or lateral approaches may be used in the thoracic spine. The devices 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 resist expulsion. Each spacer has an axial hole to allow grafting material to be packed inside the spacer.

SUSTAIN® Spacers
SUSTAIN® Spacers (including SUSTAIN® R, SUSTAIN®-IR, and SUSTAIN®-RT) are devices that can be used as intervertebral fusion devices or as vertebral body replacement devices. When used as interbody fusion devices, each of the spacers provides a different shape to accommodate various surgical approaches to the spine. SUSTAIN Small, SUSTAIN-IR, and SUSTAIN-RT Spacers are inserted using a posterior or transforaminal approach. SUSTAIN Arch Spacers are inserted using a transforaminal or lateral approach. SUSTAIN Large Spacers are inserted using an anterior, anterolateral, or lateral approach. SUSTAIN Oblique and SUSTAIN G Spacers are inserted using a posterior, transforaminal, or lateral approach. These spacers 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 resist expulsion. Each spacer has an axial hole to allow grafting material to be packed inside the spacer.

These spacers are used to provide structural stability in skeletally mature individuals following discectomy, corpectomy, or vertebrectomy (including partial). All approaches may be used in the lumbar spine; only the anterior, anterolateral, or lateral approach may be used in the thoracic spine.

Indications for Use:

PATRIOT® Spacers
PATRIOT® Spacers (including CONSTITUTION®, SIGNATURE®, CONTINENTAL®, TransContinental®, and TransContinental® M) are interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration

of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. PATRIOT® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation. All PATRIOT® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

SUSTAIN® Spacers
When used as thoracolumbar intervertebral body fusion devices, SUSTAIN® Spacers (including SUSTAIN® R, SUSTAIN®-IR, and SUSTAIN®-RT) are indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back 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) months of non-operative treatment. SUSTAIN® Spacers are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). All SUSTAIN® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

Performance Data:
Mechanical testing was conducted with the additional implants in accordance with the “Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Intervertebral Fusion Device,” June 12, 2007, ASTM F2077 (Dynamic and Static Compression and Compression-Shear) and ASTM F2267 (Subsidence), and expulsion testing was conducted to demonstrate substantial equivalence to the predicate spacers.

Clinical Literature:
Published clinical data for interbody fusion devices is provided in this submission to support the additional indications for multiple levels in the thoracolumbar spine. The clinical data demonstrates that the use of interbody fusion devices to treat patients with disc herniation, spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis or failed previous fusion (pseudarthrosis) does not pose new risks to patients.

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

Basis of Substantial Equivalence:
Subject spacers 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.