DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 22, 2017

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

Re: K152022
Trade/Device Name: SUSTAIN® R Spacers, PATRIOT® Spacers, CALIBER® Spacers, RISE® Spacers, COALITION® Spacers, COALITION AGX™ Spacers, INDEPENDENCE® Spacers, FORTIFY®-R Corpectomy Spacers, FORTIFY® I-R Corpectomy Spacers, XPand®-R Corpectomy Spacers, NIKO® Corpectomy Spacers, MONUMENT™ Spacers, ALTERA™ Spacers, MAGNIFY™ Spacers, InterContinental® Plate-Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP, ODP, OVE, OVD
Dated: February 8, 2017
Received: February 10, 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.

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" (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.

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152022

Device Name
SUSTAIN® R Spacers, PATRIOT® Spacers, CALIBER® Spacers, RISE® Spacers, COALITION® Spacers, COALITION AGX™ Spacers, INDEPENDENCE® Spacers, FORTIFY®-R Corpectomy Spacers, FORTIFY® I-R Corpectomy Spacers, XPand®-R Corpectomy Spacers, NIKO® Corpectomy Spacers, MONUMENT™ Spacers, ALTERA™ Spacers, MAGNIFY™ Spacers, InterContinental® Plate-Spacers

Indications for Use *(Describe)*

SUSTAIN® R Spacers

When used as lumbar intervertebral body fusion devices, SUSTAIN® and SUSTAIN® Radiolucent (SUSTAIN® R) Spacers are intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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 nonoperative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The SUSTAIN® and SUSTAIN® R Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the REVERE®, REVOLVE® or BEACON® Stabilization Systems.

When used as cervical intervertebral body fusion devices, the SUSTAIN® and SUSTAIN® R Spacers are intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. 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. The SUSTAIN® and SUSTAIN® R Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the ASSURE®, PROVIDENCE® or XTEND® Anterior Cervical Plate Systems.

When used as vertebral body replacement devices, SUSTAIN® and SUSTAIN® R Spacers are intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material. SUSTAIN® and SUSTAIN® R Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

PATRIOT® Spacers

Lumbar Spacers

PATRIOT® Spacers (including Constitution®, Constitution® TPS, Signature®, Signature® TPS, Continental®, Continental® TPS, TransContinental®, TransContinental® TPS, TransContinental® M and TransContinental® M TPS) are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). PATRIOT® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral 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.

Cervical Spacers

PATRIOT® Spacers (COLONIAL® ACDF) are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one level. 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 nonoperative treatment.

PATRIOT® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the ASSURE® or PROVIDENCE® Anterior Cervical Plate System.

CALIBER® Spacers
CALIBER® Spacers are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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 nonoperative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

CALIBER® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the REVERE® or REVOLVE® Stabilization Systems.

RISE® Spacers
The RISE® Spacer is a lumbar interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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 nonoperative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The RISE® Spacer is to be filled with autogenous bone graft material. This device is intended to be used with supplemental fixation, such as the REVERE® or REVOLVE® Stabilization Systems.

COALITION® and COALITION AGX™ Spacers
The COALITION® and COALITION AGX™ Spacers are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. 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 autogenous bone graft material. The COALITION® Spacer is a stand-alone interbody fusion device. The COALITION AGX™ Spacer is intended to be used with supplemental fixation such as the COALITION AGX™ Plate, ASSURE®, PROVIDENCE™, VIP®, XTEND®, or UNIFY™ Anterior Cervical Plate Systems. When used with the COALITION AGX™ Plate, the 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), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

INDEPENDENCE® Spacers
INDEPENDENCE® (including INDEPENDENCE® MIS, INDEPENDENCE® TPS, and INDEPENDENCE® MIS TPS) Spacers are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). INDEPENDENCE® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The INDEPENDENCE® Spacer is a stand-alone interbody fusion device intended to be used with three titanium alloy screws which accompany the implant.

The INDEPENDENCE® MIS Spacer is an interbody fusion device to be used with three titanium alloy screws or anchors which accompany the implants. When used with screws, the INDEPENDENCE® MIS Spacer is a stand-alone interbody

fusion device. When used with anchors, the INDEPENDENCE® MIS Spacer is intended for use with supplemental fixation (e.g. facet screws or posterior fixation). Hyperlordotic implants (≥25° lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation).

FORTIFY®-R and FORTIFY® I-R Corpectomy Spacers
FORTIFY® (FORTIFY® and FORTIFY®-R) and FORTIFY® Integrated (FORTIFY® I and FORTIFY® I-R) Corpectomy Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). These devices are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacers can be packed with autogenous bone graft or allograft. These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

XPand®-R Corpectomy Spacers
The XPand® and XPand® Radiolucent Corpectomy Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The XPand® and XPand® Radiolucent Corpectomy Spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material. The XPand® and XPand® Radiolucent Corpectomy Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

NIKO® Corpectomy Spacers
The NIKO® Corpectomy Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The NIKO® Corpectomy Spacer is intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material. The NIKO® Corpectomy Spacer is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

MONUMENT™ Spacers
The MONUMENT™ Spacer is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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 nonoperative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The MONUMENT™ Spacer is to be filled with autogenous bone graft material, and is to be used with four titanium alloy screws that accompany the implant. The device is intended to be used with supplemental fixation (i.e. pedicle screws, facet fixation).

ALTERA™ Spacers
The ALTERA™ Spacer is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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 nonoperative treatment. In addition, these patients may have up to Grade 1spondylolisthesis or retrolisthesis at the involved level(s).

The ALTERA™ Spacer is to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation.

MAGNIFY™ Spacers
The MAGNIFY™ Spacer is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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 nonoperative treatment. In addition, these patients may have up to Grade 1

spondylolisthesis or retrolisthesis at the involved level(s). The MAGNIFY™ Spacer is to be filled with autogenous bone graft material, and is to be used with supplemental fixation, such as the CREO®, REVERE® or REVOLVE® Stabilization Systems.

The MAGNIFY™-S Spacer is a stand-alone interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The MAGNIFY™-S Spacer is to be filled with autogenous bone graft material, and is to be used with three titanium alloy screws that accompany each implant.

InterContinental® Plate-Spacers

InterContinental® Plate-Spacers (including InterContinental® TPS) are lateral lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DOD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DOD 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. In addition, these patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). InterContinental® PlateSpacers are to be filled with autogenous bone graft material, and are to be used with two titanium alloy screws which accompany the implant. These devices are intended to be used with supplemental fixation (e.g. pedicle or facet screw systems) in addition to the integrated screws.

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: PEEK Devices

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: February 20, 2017

Device Name: SUSTAIN® R Spacers
PATRIOT® Spacers
CALIBER® Spacers
RISE® Spacers
COALITION® Spacers
COALITION AGX™ Spacers
INDEPENDENCE® Spacers
FORTIFY®-R Corpectomy Spacers
FORTIFY® I-R Corpectomy Spacers
XPand®-R Corpectomy Spacers
NIKO® Corpectomy Spacers
MONUMENT™ Spacers
ALTERA™ Spacers
MAGNIFY™ Spacers
InterContinental® Plate-Spacer

Classification: Per 21 CFR as follows:
§888.3060 Spinal Vertebral Body Replacement Device
and/or
§888.3080 Intervertebral Body Fusion Device

Product Code(s):

ODP	SUSTAIN® R Spacers (Cervical)
	PATRIOT® Spacers (Cervical)
	COALITION AGX™ Spacers
MAX	SUSTAIN® R Spacers (Lumbar)
	PATRIOT® Spacers (Lumbar)
	CALIBER® Spacers
	RISE® Spacers
	ALTERA™ Spacers
	MAGNIFY™ Spacers
	InterContinental® Plate-Spacer
OVE	COALITION® Spacers
	COALITION AGX™ Spacers

OVD	INDEPENDENCE® Spacers MONUMENT™ Spacers MAGNIFY™-S Spacers InterContinental® Plate-Spacer
MQP	FORTIFY®-R Corpectomy Spacers FORTIFY® I-R Corpectomy Spacers XPand®-R Corpectomy Spacers NIKO® Corpectomy Spacers SUSTAIN® R Spacers

Regulatory Class: II, Panel Code: 87

Primary Predicate: SUSTAIN® R Spacers (K040284 & K130478)

Additional Predicate(s):
PATRIOT® Spacers (Cervical) (K072991)
PATRIOT® Spacers (Lumbar) (K072970 & K122097)
PATRIOT® TransContinental® Spacer (K093242)
PATRIOT® TransContinental® M Spacer (K102313)
InterContinental® Plate-Spacer (K103382)
CALIBER® Spacers (K102293 & K123231)
COALITION® Spacers (K083389 & K131449)
COALITION AGX™ Spacers (K142218)
INDEPENDENCE® Spacers (K082252 & K120101)
MONUMENT™ Spacers (K132559)
XPand®-R Corpectomy Spacers (K060665)
FORTIFY®-R Corpectomy Spacers (K112756)
FORTIFY® I-R Corpectomy Spacers (K121107)
NIKO® Corpectomy Spacers (K072465)
RISE® Spacers (K113447)
ALTERA™ Spacers (K140411)
MAGNIFY™ Spacers (K142498)

Purpose:
The purpose of this submission is to request clearance for an additional PEEK vendor for the subject devices.

Device Descriptions:

SUSTAIN® Spacers
SUSTAIN® and SUSTAIN® Radiolucent (SUSTAIN® R) Spacers are devices that can be used as intervertebral fusion devices or as vertebral body replacement devices. These spacers are available in different shapes and heights to accommodate various surgical approaches and anatomical needs. 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). Lumbar spacers may be inserted using a posterior, transforaminal, anterior, anterolateral, or lateral lumbar approach. Cervical spacers are inserted using an anterior cervical approach.

The SUSTAIN® Spacers are made from commercially pure titanium or titanium alloy as specified in ASTM F67, F136, and F1295.The SUSTAIN® R Spacers are made from radiolucent PEEK polymer with titanium alloy or tantalum markers as specified in ASTM F136, F560, F1295, and F2026.

PATRIOT® Cervical Spacers

PATRIOT® Spacers (COLONIAL® ACDF) are cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. COLONIAL® ACDF 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. These spacers are to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

PATRIOT® Spacers are made from radiolucent polymer, with titanium alloy or tantalum markers, as specified in F2026, F136, F1295, and F560.

PATRIOT® Lumbar Spacers

PATRIOT® Spacers (including Constitution®, Constitution® TPS, Signature®, Signature® TPS, Continental®, Continental® TPS, TransContinental®, TransContinental® TPS, TransContinental® M and TransContinental® M TPS) are lumbar 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 lumbar spine. Constitution® PLIF Spacers are inserted using a posterior approach. Signature® TLIF Spacers are inserted using a transforaminal approach. Continental® ALIF Spacers are inserted using an anterior approach. Transcontinental® and TransContinental® M Spacers are inserted using an anterior or lateral approach. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. These spacers are to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

PATRIOT® Spacers are made from PEEK radiolucent polymer (ASTM F2026) with titanium alloy or tantalum markers (ASTM F560). Signature® R Spacers

also include an internal titanium alloy or commercially pure titanium (ASTM F67) component, and TransContinental® M Spacers also include an integrated titanium alloy nut. The Signature® Ti Spacer is made from titanium alloy or commercially pure titanium. The titanium alloy is TAV (ASTM F136) or TAN (ASTM F1295). PATRIOT® TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

InterContinental® Plate-Spacer

InterContinental® Plate-Spacers (including InterContinental® TPS) are lateral lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. InterContinental® Plate-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 grip the endplates of the adjacent vertebrae to aid in expulsion resistance. InterContinental® Plate-Spacers are to be filled with autogenous bone graft material, and are to be used with titanium alloy bone screws, with or without hydroxyapatite coating. Bone screws are used to attach to the lateral portion of the adjacent vertebral bodies for bony fixation.

The spacers in the InterContinental® Plate-Spacers are manufactured from radiolucent polymer, with titanium alloy or tantalum markers, as specified in ASTM F136, F560, F1295, and F2026. The plates in the InterContinental® Plate-Spacers are manufactured from titanium alloy, as specified in ASTM F136 and F1295. The screws in the InterContinental® Plate-Spacers are manufactured from titanium alloy, as specified in ASTM F136 and F1295, and are available with or without hydroxyapatite (HA) coating, as specified in ASTM F1185. InterContinental® TPS Plate-Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

CALIBER® Spacers

CALIBER® Spacers are lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. CALIBER® Spacers provide different shapes to accommodate various surgical approaches to the lumbar spine (posterior, transforaminal [posterolateral] or lateral). The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. These spacers are to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

CALIBER® Spacers are manufactured from radiolucent PEEK polymer and titanium alloy per ASTM F2026, F136 and F1295; non-expandable CALIBER® Spacers are manufactured from PEEK only. CALIBER® Spacers contain radiopaque titanium alloy or tantalum markers as specified in ASTM F136, F1295 and F560.

COALITION® Spacers

The COALITION® and COALITION AGX™ Spacers are a 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 spacer is to be filled with autogenous bone graft material. 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. The COALITION® Spacer and the COALITION AGX™ Spacer used with a COALITION AGX™ Plate are stand-alone cervical interbody fusion devices. Screws are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation.

The COALITION® and COALITION AGX™ Spacers are manufactured radiolucent PEEK polymer, with titanium alloy or tantalum markers, as specified in ASTM F2026 F136, F1295 and F560. The plates are made from titanium alloy, as specified in ASTM, F136, F1295, and F1472. The screws are manufactured from titanium alloy, as specified in ASTM F136 and F1295.

INDEPENDENCE® Spacers

INDEPENDENCE® (including INDEPENDENCE® MIS, INDEPENDENCE® TPS, and INDEPENDENCE® MIS TPS) Spacers are anterior lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The 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 aid in expulsion resistance. Screws are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation. The INDEPENDENCE® MIS Spacer may also be used with anchors inserted through the anterior titanium portion of the implants into adjacent vertebral bodies for bony fixation.

INDEPENDENCE® and INDEPENDENCE® MIS Spacers are made from titanium alloy and radiolucent polymer with titanium alloy or tantalum markers, as specified in ASTM F136, F560, F1295, and F2026. INDEPENDENCE® MIS Spacers are additionally available in an all titanium alloy version. All PEEK implants are additionally available with a commercially pure titanium plasma spray coating (TPS), as specified in ASTM F1580 and F67. The screws and anchors are manufactured from titanium alloy, as specified in ASTM F136 and F1295, and the screws and anchors are available with or without hydroxyapatite (HA) coating, as specified in ASTM F1185.

MONUMENT™ Spacers

The MONUMENT™ Spacer is an anterior lumbar interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy. The MONUMENT™ Spacer is intended to aid in reduction of a Grade 1 spondylolisthesis. The 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 aid in expulsion resistance. Screws are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation. The spacer is to be filled with autogenous bone graft material.

The MONUMENT™ Spacer is made from PEEK radiolucent polymer and titanium alloy, as specified in ASTM F136, F1295, and F2026. The mating screws are manufactured from titanium alloy, as specified in ASTM F136 and F1295, and are available with hydroxyapatite (HA) coating, as specified in ASTM F1185.

XPand® Corpectomy Spacers

The XPand® and XPand® Radiolucent Corpectomy Spacer devices are vertebral body replacement devices used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The system is comprised of spacers of various heights and footprints to fit the anatomical needs of a wide variety of patients. Each spacer has an axial hole to allow grafting material to be packed inside of the spacer. Protrusions on the superior and inferior surfaces of each device will grip the endplates of the adjacent vertebrae to resist expulsion.
The XPand® devices are made from titanium alloy as specified in F136 and F1295.

The XPand® Radiolucent Corpectomy Spacer devices are made from radiolucent polymer and titanium alloy as specified in ASTM F2026, F136 and F1295, and include markers made from titanium alloy or tantalum as specified in ASTM F136, F1295 and F560.

FORTIFY® Corpectomy Spacers

FORTIFY® and FORTIFY® Integrated Corpectomy Spacers are vertebral body replacement devices used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The components 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 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 to be packed inside of the spacer. Protrusions (teeth) on the superior and inferior surfaces grip the endplates of the adjacent vertebrae to resist expulsion. Additional spikes are available on some implants.

FORTIFY® Integrated endplates have an integrated plate to accommodate screws for additional fixation and are assembled to the core.

FORTIFY® and FORTIFY® I Corpectomy Spacers are manufactured from titanium alloy per ASTM F136 and F1295. FORTIFY®-R and FORTIFY® I-R Corpectomy Spacers are manufactured from radiolucent PEEK OPTIMA LT1, with titanium alloy and tantalum components, per ASTM F2026, F136, F1295, and F560. Screws are manufactured from titanium alloy per ASTM F136 and F1295, with or without hydroxyapatite coating per ASTM F1185.

NIKO® Corpectomy Spacers

The NIKO® Corpectomy Spacer device is a vertebral body replacement device used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The system is comprised of spacers of various fixed heights to fit the anatomical needs of a variety of patients. Each spacer has an axial hole to allow grafting material to be packed inside of the spacer. Protrusions on the superior and inferior surfaces of each device will grip the endplates of the adjacent vertebrae to resist expulsion.

The NIKO® Corpectomy Spacer device is made from radiolucent polymer and titanium alloy or tantalum as specified in ASTM F2026, F136, F1295, and F560.

RISE® Spacers

RISE® Spacers are lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. RISE® Spacers are provided in different shapes to accommodate various surgical approaches to the lumbar spine (posterior, transforaminal [posterolateral] or lateral) and can expand to the desired height. The implants are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. This device is to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

RISE® Spacers are manufactured from titanium alloy, as specified in ASTM F136 and F1295. An internal component is manufactured from radiolucent PEEK polymer, as specified in ASTM F2026.

ALTERA™ Spacers

The ALTERA™ Spacer is an expandable lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The ALTERA™ Spacer accommodates various surgical approaches to the lumbar spine (posterior or transforaminal [posterolateral]) and allows articulation upon insertion. The devices are available in various height ranges, allowing continuous expansion within the range, to fit the anatomical needs of a wide variety of patients. This device is to be filled with autogenous bone graft material. Protrusions on the superior and inferior

surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

The ALTERA™ Spacer is made from titanium alloy, as specified in ASTM F136, F1295, and F1472. Internal components are made from radiolucent PEEK polymer and cobalt chromium molybdenum alloy, as specified in ASTM F2026 and F1537, respectively.

MAGNIFY™ Spacers

MAGNIFY™ Spacers are expandable anterior lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The devices are available in various height expansion ranges 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. These devices are to be filled with autogenous bone graft material.

The MAGNIFY™ Spacer is to be used with supplemental fixation. The MAGNIFY™-S Spacer is to be used with three titanium alloy screws that accompany the implant.

MAGNIFY™ Spacers are manufactured from titanium alloy, as specified in ASTM F136, and include an internal component manufactured from radiolucent PEEK polymer, as specified in ASTM F2026. The screws used with MAGNIFY™-S are manufactured from titanium alloy, as specified in ASTM F136 and F1295, and are available with hydroxyapatite (HA) coating, as specified in ASTM F1185.

Indications for Use:

SUSTAIN® Spacers

When used as lumbar intervertebral body fusion devices, SUSTAIN® and SUSTAIN® Radiolucent (SUSTAIN® R) Spacers are intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The SUSTAIN® and SUSTAIN® R Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the REVERE®, REVOLVE® or BEACON® Stabilization Systems.

When used as cervical intervertebral body fusion devices, the SUSTAIN® and SUSTAIN® R Spacers are intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level.

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. The SUSTAIN® and SUSTAIN® R Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the ASSURE®, PROVIDENCE® or XTEND® Anterior Cervical Plate Systems.

When used as vertebral body replacement devices, SUSTAIN® and SUSTAIN® R Spacers are intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material. SUSTAIN® and SUSTAIN® R Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

PATRIOT® Cervical Spacers

PATRIOT® Spacers (COLONIAL® ACDF) are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one level. 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.

PATRIOT® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the ASSURE® or PROVIDENCE® Anterior Cervical Plate System.

PATRIOT® Lumbar Spacers

PATRIOT® Spacers (including Constitution®, Constitution® TPS, Signature®, Signature® TPS, Continental®, Continental® TPS, TransContinental®, TransContinental® TPS, TransContinental® M and TransContinental® M TPS) are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). PATRIOT® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral 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.

InterContinental® Plate-Spacer

InterContinental® Plate-Spacers (including InterContinental® TPS) are lateral lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). InterContinental® Plate-Spacers are to be filled with autogenous bone graft material, and are to be used with two titanium alloy screws which accompany the implant. These devices are intended to be used with supplemental fixation (e.g. pedicle or facet screw systems) in addition to the integrated screws.

CALIBER® Spacers

CALIBER® Spacers are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

CALIBER® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the REVERE® or REVOLVE® Stabilization Systems.

COALITION® Spacers

The COALITION® and COALITION AGX™ Spacers are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. 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 autogenous bone graft material. The COALITION® Spacer is a stand-alone interbody fusion device. The COALITION AGX™ Spacer is intended to be used with supplemental fixation such as the COALITION AGX™ Plate, ASSURE®, PROVIDENCE™, VIP®, XTEND®, or UNIFY™ Anterior Cervical Plate Systems. When used with the COALITION AGX™ Plate, the 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), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

INDEPENDENCE® Spacers

INDEPENDENCE® (including INDEPENDENCE® MIS, INDEPENDENCE® TPS, and INDEPENDENCE® MIS TPS) Spacers are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). INDEPENDENCE® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The INDEPENDENCE® Spacer is a stand-alone interbody fusion device intended to be used with three titanium alloy screws which accompany the implant. The INDEPENDENCE® MIS Spacer is an interbody fusion device to be used with three titanium alloy screws or anchors which accompany the implants. When used with screws, the INDEPENDENCE® MIS Spacer is a stand-alone interbody fusion device. When used with anchors, the INDEPENDENCE® MIS Spacer is intended for use with supplemental fixation (e.g. facet screws or posterior fixation). Hyperlordotic implants (≥25° lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation).

MONUMENT™ Spacers

The MONUMENT™ Spacer is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The MONUMENT™ Spacer is to be filled with autogenous bone graft material, and is to be used with four titanium alloy screws that accompany the implant. The device is intended to be used with supplemental fixation (i.e. pedicle screws, facet fixation).

XPand® Corpectomy Spacers

The XPand® and XPand® Radiolucent Corpectomy Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The XPand® and XPand® Radiolucent Corpectomy Spacers are intended to be used with supplemental spinal fixation systems that

have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material. The XPand® and XPand® Radiolucent Corpectomy Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

FORTIFY® Corpectomy Spacers

FORTIFY® (FORTIFY® and FORTIFY®-R) and FORTIFY® Integrated (FORTIFY® I and FORTIFY® I-R) Corpectomy Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). These devices are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacers can be packed with autogenous bone graft or allograft. These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

NIKO® Corpectomy Spacers

The NIKO® Corpectomy Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The NIKO® Corpectomy Spacer is intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material. The NIKO® Corpectomy Spacer is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

RISE® Spacers

The RISE® Spacer is a lumbar interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The RISE® Spacer is to be filled with autogenous bone graft material. This device is intended to be used with supplemental fixation, such as the REVERE® or REVOLVE® Stabilization Systems.

ALTERA™ Spacers

The ALTERA™ Spacer is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The ALTERA™ Spacer is to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation.

MAGNIFY™ Spacers

The MAGNIFY™ Spacer is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The MAGNIFY™ Spacer is to be filled with autogenous bone graft material, and is to be used with supplemental fixation, such as the CREO®, REVERE® or REVOLVE® Stabilization Systems.

The MAGNIFY™-S Spacer is a stand-alone interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The MAGNIFY™-S Spacer is to be filled with autogenous bone graft material, and is to be used with three titanium alloy screws that accompany each implant.

Basis of Substantial Equivalence:

The subject devices have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. Performance testing was assessed by comparing the mechanical performance of subject and predicate systems per ASTM F2077. The information provided within this premarket notification supports substantial equivalence of the subject devices to the predicate devices. The subject devices perform as well as or better than the predicate devices.