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

December 21, 2017

Re: K171848
Trade/Device Name: FORTIFY® and FORTIFY® Integrated Corpectomy Spacers, XPand® Corpectomy Spacers, NIKO® Corpectomy Spacers, SUSTAIN® Spacers, COALITION® Spacers, PATRIOT® Lumbar Spacers, PATRIOT® Cervical Spacers, ALTERA™ Spacers, RISE® Spacers, CALIBER® Spacers, ELSA™ Spacers, LATIS® Spacers, MONUMENT™ Spacers, InterContinental® Plate-Spacers, MAGNIFY™ Spacers, INDEPENDENCE® Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVD, MQP, PLR, ODP, OVE, KWQ
Dated: November 17, 2017
Received: November 20, 2017

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. 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171848

Device Name
FORTIFY® and FORTIFY® Integrated 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)

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510(k) Number *(if known)*
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Device Name
XPand® Corpectomy Spacers

Indications for Use *(Describe)*
XPand® Corpectomy Spacers (including XPand®-R) 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). XPand® 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 system, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material. XPand® Corpectomy Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. All XPand® 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)

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Device Name
NIKO® Corpectomy Spacers

Indications for Use *(Describe)*
NIKO® 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). NIKO® 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 spacers can be packed with bone grafting material. NIKO® Corpectomy Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. All NIKO® 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)

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510(k) Number *(if known)*
K171848

Device Name
SUSTAIN® Spacers

Indications for Use *(Describe)*

When used as lumbar intervertebral body fusion devices, SUSTAIN® Spacers (including SUSTAIN® R, and SUSTAIN®-IR) 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). SUSTAIN®, SUSTAIN® R and SUSTAIN®-IR Spacers are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. SUSTAIN® TPS Spacers are to be used with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the CREO®, REVERE®, REVOLVE®, or BEACON® Stabilization Systems.

When used as cervical intervertebral body fusion devices, SUSTAIN® Spacers (including SUSTAIN® R) 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. SUSTAIN® 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. All SUSTAIN® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

When used as vertebral body replacement devices, SUSTAIN® Spacers (including SUSTAIN® and SUSTAIN® R TPS) 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 spacers can be packed with bone grafting material. SUSTAIN® Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. 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)

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510(k) Number *(if known)*
K171848

Device Name
COALITION® Spacers

Indications for Use *(Describe)*
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. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone, depending on the system.

The COALITION® Spacer is a stand-alone interbody fusion device intended for use at one or two levels of the cervical spine (C2-T1) and is to be used with two titanium alloy screws which accompany the implant. The spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The COALITION MIS™ Spacer is an interbody fusion device and is to be used with two titanium alloy screws 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. The spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The COALITION AGX™ Spacer is intended to be used with supplemental fixation, such as anterior cervical plates or posterior cervical screw fixation. 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 and Spacer assembly is a stand-alone device intended for use at one level of the cervical spine (C2-T1) and is to be used with two titanium alloy screws which accompany the implant. The spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

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.

COALITION® TPS Spacers are stand-alone interbody fusion devices intended for use at one level of the cervical spine (C2-T1) and are to be used with two titanium alloy screws which accompany the implants. The spacers are to be filled with autogenous bone graft.

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)

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510(k) Number *(if known)*
K171848

Device Name
PATRIOT® Lumbar Spacers

Indications for Use *(Describe)*
PATRIOT® Spacers (including Constitution®, Signature®, Continental®, TransContinental®, and TransContinental® M) 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. 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)

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510(k) Number *(if known)*
K171848

Device Name
PATRIOT® Cervical Spacers

Indications for Use *(Describe)*
PATRIOT® Spacers (including COLONIAL®) 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 as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. All PATRIOT® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

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 Systems.

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)

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510(k) Number *(if known)*
K171848

Device Name
ALTERA™ Spacers

Indications for Use *(Describe)*
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.

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)

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510(k) Number *(if known)*
K171848

Device Name
RISE® Spacers

Indications for Use *(Describe)*
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.

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)

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See PRA Statement below.

510(k) Number *(if known)*
K171484

Device Name
CALIBER® Spacers

Indications for Use *(Describe)*
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). All CALIBER® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

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

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)

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510(k) Number *(if known)*
K171848

Device Name
ELSA™ Spacers

Indications for Use *(Describe)*
The ELSA™ 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 ELSA™ Spacer is to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone, may be used with two bone screws, and is to be used with supplemental fixation. Hyperlordotic (≥20°) implants must be used with the two bone screws and supplemental fixation in addition to the bone 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)

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510(k) Number *(if known)*
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Device Name
LATIS® Spacers

Indications for Use *(Describe)*

LATIS® 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).

LATIS® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K171848

Device Name
MONUMENT™ Spacers

Indications for Use *(Describe)*
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).

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K171848

Device Name
InterContinental® Plate-Spacers

Indications for Use *(Describe)*
InterContinental® Plate-Spacers 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. All InterContinental® 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)

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Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K171848

Device Name
MAGNIFY™ Spacers

Indications for Use *(Describe)*

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.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K171848

Device Name
INDEPENDENCE® Spacers

Indications for Use *(Describe)*
INDEPENDENCE® (including INDEPENDENCE MIS™, and INDEPENDENCE MIS AGX™ 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. All INDEPENDENCE® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

INDEPENDENCE® are stand-alone interbody fusion devices intended to be used with three titanium alloy screws which accompany the implants.

INDEPENDENCE MIS™ are interbody fusion devices intended to be used with three titanium alloy screws or anchors which accompany the implants. When used with screws, these devices are stand-alone interbody fusion devices. When used with anchors, these devices are 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).

INDEPENDENCE MIS AGX™ Integrated Spacer and INDEPENDENCE MIS AGX™ Integrated Ti Spacer are interbody fusion devices that may be used with three titanium alloy screws or anchors which accompany the implants. When used with screws, these devices are stand-alone interbody fusion devices. When used with anchors, these devices are 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).

INDEPENDENCE MIS AGX™ Spacers are C-shaped, non-integrated PEEK spacers that are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation). When used in conjunction with the INDEPENDENCE MIS AGX™ Integrated Ti Spacer, these devices become the INDEPENDENCE MIS AGX™ Integrated Spacer.

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)

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510(k) Summary: MRI Compatibility for Intervertebral Fusion and Vertebral Body Replacement Implants

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

Primary Contact: Lori Burns
Director of Regulatory Affairs

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

Date Prepared: December 20, 2017

Device Name: FORTIFY® and FORTIFY® Integrated Corpectomy Spacers
XPand® Corpectomy Spacers
NIKO® Corpectomy Spacers
SUSTAIN® Spacers
COALITION® Spacers
PATRIOT® Lumbar Spacers
PATRIOT® Cervical Spacers
ALTERA™ Spacers
RISE® Spacers
CALIBER® Spacers
ELSA™ Spacers
LATIS® Spacers
MONUMENT™ Spacers
InterContinental® Plate-Spacers
MAGNIFY™ Spacers
INDEPENDENCE® Spacers

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

PLR FORTIFY® Corpectomy Spacers
MQP FORTIFY® and FORTIFY® Integrated Corpectomy Spacers
XPand® Corpectomy Spacers
NIKO® Corpectomy Spacers
SUSTAIN® Spacers (Cervical & Lumbar)
MAX SUSTAIN® Spacers (Lumbar)
PATRIOT® Spacers (Lumbar)

	TransContinental® M
	ALTERA™ Spacers
	RISE® Spacers
	CALIBER® Spacers
	LATIS® Spacers
	MAGNIFY™ Spacers
	INDEPENDENCE® Spacers
ODP	SUSTAIN® Spacers (Cervical)
	COALITION AGX™ Spacers
	PATRIOT® Spacers (Cervical)
OVE	COALITION® Spacers
	COALITION AGX™ Spacers
KWQ	COALITION AGX™ Spacer
OVD	ELSA™ Spacers
	MONUMENT™ Spacers
	InterContinental® Plate-Spacer
	MAGNIFY™ Spacers
	INDEPENDENCE® Spacers

Regulatory Class: II, Panel Code: 87

Primary Predicate: FORTIFY® I Corpectomy Spacers (K121107)

Additional Predicates:

FORTIFY® Corpectomy Spacers (K112756)
XPand® Corpectomy Spacers (K060665)
NIKO® Corpectomy Spacers (K072465)
SUSTAIN® Spacers (K130478 & K151665)
COALITION® Spacers (K151939)
PATRIOT® Spacers (Lumbar) (K122097, K161223)
PATRIOT® Spacers (Cervical) (K072991)
ALTERA® Spacers (K140411)
RISE® Spacers (K113447)
CALIBER® Spacers (K123231)
ELSA™ Spacers (K161379)
LATIS® Spacers (K123913)
MONUMENT® Spacers (K132559)
InterContinental® Plate-Spacer (K103382, K161223)
MAGNIFY™ Spacers (K142498)
INDEPENDENCE® Spacers (K160597, K170157)
TPS Spacers (K143578)

Purpose:
The purpose of this 510(k) is to update the labeling for MRI compatibility.

Device Description:
Globus Medical's interbody fusion and vertebral body replacement devices are cervical, thoracic or lumbar devices used to provide structural stability in skeletally mature individuals following discectomy, corpectomy or vertebrectomy and may be inserted using an anterior, posterior, lateral or transforaminal approach. The devices are available in various heights and geometric options to accommodate surgical approaches and patient anatomy. Ridges on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion. These devices are to be used in conjunction with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to be packed inside the device.

These devices are made from radiolucent PEEK polymer with titanium alloy or tantalum markers or titanium alloy, commercially pure titanium, titanium alloy, and cobalt chromium molybdenum al. Implants are also available with hydroxyapatite (HA) coating.

Indications for Use:
FORTIFY® and FORTIFY® Integrated Corpectomy Spacers
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.

XPand® Corpectomy Spacers

XPand® Corpectomy Spacers (including XPand®-R) 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). XPand® 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 system, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material. XPand® Corpectomy Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. All XPand® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

NIKO® Corpectomy Spacers

NIKO® 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). NIKO® 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 spacers can be packed with bone grafting material. NIKO® Corpectomy Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. All NIKO® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

SUSTAIN® Spacers

When used as lumbar intervertebral body fusion devices, SUSTAIN® Spacers (including SUSTAIN® R, and SUSTAIN®-IR) 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). SUSTAIN®, SUSTAIN® R and SUSTAIN®-IR Spacers are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. SUSTAIN® TPS Spacers are to be used with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the CREO®, REVERE®, REVOLVE®, or BEACON® Stabilization Systems.

When used as cervical intervertebral body fusion devices, SUSTAIN® Spacers (including SUSTAIN® R) 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. SUSTAIN® 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. All SUSTAIN® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

When used as vertebral body replacement devices, SUSTAIN® Spacers (including SUSTAIN® and SUSTAIN® R TPS) 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 spacers can be packed with bone grafting material. SUSTAIN® Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. All SUSTAIN® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

COALITION® Spacers

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. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone, depending on the system.

The COALITION® Spacer is a stand-alone interbody fusion device intended for use at one or two levels of the cervical spine (C2-T1) and is to be used with two titanium alloy screws which accompany the implant. The spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The COALITION MIS™ Spacer is an interbody fusion device and is to be used with two titanium alloy screws 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. The spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The COALITION AGX™ Spacer is intended to be used with supplemental fixation, such as anterior cervical plates or posterior cervical screw fixation. 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 and Spacer assembly is a stand-alone device intended for use at one level of the cervical spine (C2-T1) and is to be used with two titanium alloy screws which accompany the implant. The spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

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.

COALITION® TPS Spacers are stand-alone interbody fusion devices intended for use at one level of the cervical spine (C2-T1) and are to be used with two titanium alloy screws which accompany the implants. The spacers are to be filled with autogenous bone graft.

PATRIOT® Lumbar Spacers

PATRIOT® Spacers (including Constitution®, Signature®, Continental®, TransContinental®, and TransContinental® M) 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. All PATRIOT® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

PATRIOT® Cervical Spacers

PATRIOT® Spacers (including COLONIAL®) 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 as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. All PATRIOT® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

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 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.

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.

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). All CALIBER® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

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

ELSA™ Spacers

The ELSA™ 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 ELSA™ Spacer is to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone, may be used with two bone screws, and is to be used with supplemental fixation. Hyperlordotic (≥20°) implants must be used with the two bone screws and supplemental fixation in addition to the bone screws.

LATIS® Spacers

LATIS® 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).

LATIS® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental 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).

InterContinental® Plate-Spacers

InterContinental® Plate-Spacers 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. All InterContinental® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

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.

INDEPENDENCE® Spacers

INDEPENDENCE® (including–INDEPENDENCE MIS™, and INDEPENDENCE MIS AGX™ 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. All INDEPENDENCE® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

INDEPENDENCE® are stand-alone interbody fusion devices intended to be used with three titanium alloy screws which accompany the implants.

INDEPENDENCE MIS™ are interbody fusion devices intended to be used with three titanium alloy screws or anchors which accompany the implants. When used with screws, these devices are stand-alone interbody fusion devices. When used with anchors, these devices are 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).

INDEPENDENCE MIS AGX™ Integrated Spacer and INDEPENDENCE MIS AGX™ Integrated Ti Spacer are interbody fusion devices that may be used with three titanium alloy screws or anchors which accompany the implants. When used with screws, these devices are stand-alone interbody fusion devices. When used with anchors, these devices are 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).

INDEPENDENCE MIS AGX™ Spacers are C-shaped, non-integrated PEEK spacers that are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation). When used in conjunction with the INDEPENDENCE MIS AGX™ Integrated Ti Spacer, these devices become the INDEPENDENCE MIS AGX™ Integrated Spacer.

Summary of Technological Characteristics as Compared to the Predicate
The technological characteristics remain the same between the subject devices and the predicate devices. No changes have been made to any of the devices. This submission is only to update the labeling to include Magnetic Resonance Imaging (MRI) information.

Performance Data:
MRI testing was performed on the subject devices per the following ASTM Standards:

- ASTM F2052:2006 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2119:2007 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- ASTM F2182:11a Standard Test Method of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2213:2006 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

No further device performance testing was required for this submission. The performance testing remains the same for the subject and predicate devices.

No further sterilization, biocompatibility and endotoxin evaluation and/or testing were required for this submission. The sterilization, biocompatibility and endotoxin testing remains the same for the subject and predicate devices.

Basis of Substantial Equivalence:
The subject devices are substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use.