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

Re: K170157
Trade/Device Name: INDEPENDENCE® Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: August 25, 2017
Received: August 28, 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 (DICE) 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 (DICE) 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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K170157

Device Name
INDEPENDENCE® Spacers

Indications for Use (Describe)
INDEPENDENCE® (including INDEPENDENCE® TPS, INDEPENDENCE MISTM, INDEPENDENCE MISTM TPS, INDEPENDENCE MIS AGXTM, and INDEPENDENCE MIS AGXTM 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.

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

INDEPENDENCE MISTM and INDEPENDENCE MISTM TPS Spacers 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 AGXTM Integrated Spacer, INDEPENDENCE MIS AGXTM TPS Integrated Spacer, and INDEPENDENCE MIS AGXTM 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 AGXTM Spacer and INDEPENDENCE MIS AGXTM TPS Spacer 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 AGXTM Integrated Ti Spacer, these devices become the INDEPENDENCE MIS AGXTM Integrated Spacers.

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.
This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: INDEPENDENCE® Additional Implants

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: August 25, 2017

Device Name: INDEPENDENCE® Spacers

Common Name: Intervertebral Fusion Device With Integrated Fixation, Lumbar
              Intervertebral Fusion Device With Bone Graft, Lumbar

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

Primary Predicate: INDEPENDENCE® MIS Spacers (K160597)

Additional Predicates:
INDEPENDENCE® Spacers (K082252, K120101)
BAK INTERBODY FUSION SYSTEM (P950002, K142397)
TPS Spacers (K143578)
MAGNIFY Spacers (K142498)

Reference Device: COALITION® AGX (K142218)

Purpose:
The purpose of this submission is to request clearance for the following implants:
- INDEPENDENCE MIS AGX™ Integrated Spacer
- INDEPENDENCE MIS AGX™ TPS Integrated Spacer
- INDEPENDENCE MIS AGX™ Integrated Ti Spacer
- INDEPENDENCE MIS AGX™ Spacer
- INDEPENDENCE MIS AGX™ TPS Spacer

Device Description:
INDEPENDENCE MIS AGX™ 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 the device grip the endplates of the adjacent vertebrae to aid in expulsion resistance. INDEPENDENCE MIS AGX™ Spacers are to be filled...
with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. INDEPENDENCE MIS AGX™ Integrated Spacers may be used with three titanium alloy screws and/or anchors which accompany the implants.

The INDEPENDENCE MIS AGX™ Integrated Ti Spacer is made from titanium alloy as specified in ASTM F136, F1295, and F1472. INDEPENDENCE MIS AGX™ Spacers are made from radiolucent polymer, with titanium alloy or tantalum markers, as specified in ASTM F2026, F136, F1295, and F560. All PEEK implants are additionally available with a commercially pure titanium plasma spray coating, as specified in ASTM F67 and ASTM F1580.

The mating 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.

**Indications for Use:**
INDEPENDENCE® (including INDEPENDENCE® TPS, INDEPENDENCE MIS™, INDEPENDENCE MIS™ TPS, INDEPENDENCE MIS AGX™, and INDEPENDENCE MIS AGX™ 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.

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

INDEPENDENCE MIS™ and INDEPENDENCE MIS™ TPS Spacers 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, INDEPENDENCE MIS AGX™ TPS 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™ Spacer and INDEPENDENCE MIS AGX™ TPS Spacer 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.

**Performance Data:**
Mechanical testing (static and dynamic compression and compression-shear, subsidence, and expulsion) was conducted in accordance with the “Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Intervertebral Fusion Device,” June 12, 2007, ASTM F2077, and ASTM F2267 to demonstrate substantial equivalence to the predicate spacers. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011.

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

**Basis of Substantial Equivalence:**
INDEPENDENCE MIS AGX™ Implants have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject spacers to the predicate devices.