



Food and Drug Administration  
10903 New Hampshire Avenue  
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August 29, 2016

Globus Medical, Incorporated  
Kelly J. Baker, Ph.D.  
Senior Vice President, Regulatory and Clinical Affairs  
2560 General Armistead Avenue  
Audubon, Pennsylvania 19403

Re: K160597

Trade/Device Name: INDEPENDENCE<sup>®</sup> MIS Spacers

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral body fusion device

Regulatory Class: Class II

Product Code: OVD, MAX

Dated: July 27, 2016

Received: July 28, 2016

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 Parts 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" (21CFR 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,

**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**

510(k) Number (if known)

K160597

Device Name

INDEPENDENCE® MIS Spacers

Indications for Use (Describe)

INDEPENDENCE® (including INDEPENDENCE® MIS) Spacers 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 ( $\geq 25^\circ$  lordosis) are intended for use with supplemental fixation (e.g. facet screws or 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

## **510(k) Summary: INDEPENDENCE® MIS Spacers**

**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:** July 27, 2016

**Device Name:** INDEPENDENCE® MIS Spacers

**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® Spacers (K082252)

**Additional Predicates:** INDEPENDENCE® Spacers (K120101)  
ROI-A Implant System (K110327)  
STALIF TT (K150643)  
Brigade Hyperlordotic System (K123045)

### **Purpose:**

The purpose of this submission is to request clearance for additional INDEPENDENCE® MIS implants; and to update indications for use with allogenic bone graft for all INDEPENDENCE® Spacers.

### **Device Description:**

INDEPENDENCE® MIS 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. Screws and/or anchors are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation.

INDEPENDENCE® MIS Spacers are made from titanium alloy, or titanium alloy and radiolucent polymer with titanium alloy or tantalum markers, as specified in ASTM F136, F560, F1295, and F2026. All PEEK implants are additionally available with a commercially pure titanium plasma spray coating, as specified in 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<sup>®</sup> (including INDEPENDENCE<sup>®</sup> MIS) 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<sup>®</sup> Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The INDEPENDENCE<sup>®</sup> Spacer is a stand-alone interbody fusion device intended to be used with three titanium alloy screws which accompany the implant. The INDEPENDENCE<sup>®</sup> 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<sup>®</sup> MIS Spacer is a stand-alone interbody fusion device. When used with anchors, the INDEPENDENCE<sup>®</sup> MIS Spacer is intended for use with supplemental fixation (e.g. facet screws or posterior fixation). Hyperlordotic implants ( $\geq 25^\circ$  lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation).

**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.

**Technological Characteristics:**

INDEPENDENCE MIS 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<sup>®</sup> MIS Spacers have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject spacers to the predicate devices.