DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 15, 2016

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

Re: K161223
Trade/Device Name: TransContinental® M Spacers and InterContinental® Plate-Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: June 23, 2016
Received: June 27, 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 yours,

Mark N. Melkerson -S

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)*
K161223

Device Name
TransContinental® M Spacers

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K161223

Device Name
InterContinental® Plate-Spacers

Indications for Use *(Describe)*

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.

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: **TransContinental® M and InterContinental® 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: June 23, 2016

Device Name: TransContinental® M Spacers
InterContinental® Plate-Spacers

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

Primary Predicate: NuVasive CoRoent (K140479 & K141665)

Additional Predicates: TransContinental® M Spacers (K102313 & K122097)
InterContinental® Plate-Spacer (K103382)
TPS Spacers (K143578)

Purpose:
The purpose of this submission is to request clearance for TransContinental® M and InterContinental® Additional Implants.

Device Description:

PATROT® 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-Spacers

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.

Indications for Use:

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-Spacers

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.

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 and provided in the predicate submissions to demonstrate substantial equivalence. Additional expulsion testing and cadaver studies were performed to demonstrate equivalence of the subject devices.

Basis of Substantial Equivalence:

TransContinental® M and InterContinental® Additional 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 to the predicate devices. TransContinental® M and InterContinental® Additional Implants are as safe, as effective, and perform as well as or better than the predicate devices.