DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 16, 2016

Globus Medical Incorporated
% Dr. Kelly Baker
Senior Vice President, Regulatory and Clinical Affairs
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K151665
Trade/Device Name: SUSTAIN® Additional Implants
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: February 12, 2016
Received: February 16, 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)*
K151665

Device Name
SUSTAIN® Additional Implants

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® Spacers are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. 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)

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)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: SUSTAIN® 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: March 15, 2016

Device Name: SUSTAIN® Additional Implants

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

Primary Predicate: SUSTAIN® Spacers (K130478)

Additional Predicates: CALIBER® Spacer (K102293 & K123231)
Medtronic Capstone Control (K120368)
NuVasive CoRoent (K100043)
Stryker AVS PL PEEK Spacers (K143163)

Purpose:
The purpose of this submission is to request clearance for SUSTAIN® Additional Implants (SUSTAIN®-IR Spacers) and to update indications for use with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft for SUSTAIN® Spacers (including SUSTAIN® R and SUSTAIN®-IR).

Device Description:
SUSTAIN®-IR Spacers are lumbar intervertebral fusion devices used to provide structural stability in skeletally mature individuals following discectomy and may be inserted using a posterior or transforaminal approach. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. SUSTAIN®-IR Spacers are inserted into the disc space and rotated 90° to the final position. Ridges on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion. SUSTAIN®-IR Spacers have an axial hole to allow autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to be packed inside the spacer.

SUSTAIN®-IR Spacers are made from radiolucent PEEK polymer with titanium alloy or tantalum markers as specified in ASTM F136, F560, F1295, and F2026.

Indications for Use:
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® Spacers are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These devices are intended to be used with supplemental fixation.

Performance Data:
Mechanical testing (static and dynamic compression, static and dynamic compression-shear, and subsidence) 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 devices. A cadaver implantation study was also performed to demonstrate feasibility of device insertion and assess potential endplate damage.

Basis of Substantial Equivalence:
SUSTAIN® 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. SUSTAIN® Additional Implants are as safe, as effective, and perform as well as or better than the predicate devices.