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 14, 2017

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

Re: K171413
Trade/Device Name: HAVEN™ Laminoplasty System,
CANOPY® Laminoplasty Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: May 12, 2017
Received: May 15, 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 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 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

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)*
K171413

Device Name
HAVEN™ Laminoplasty System

Indications for Use *(Describe)*
The HAVEN™ Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The HAVEN™ Laminoplasty System is used to hold bone allograft or autograft material in place in order to prevent the graft from expulsion or impinging the spinal cord.

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.

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:

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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)*
K171413

Device Name
CANOPY® Laminoplasty Fixation System

Indications for Use *(Describe)*
The CANOPY® Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The CANOPY® Laminoplasty Fixation System is used to hold bone allograft or autograft material in place in order to prevent the graft from expulsion or impinging the spinal cord.

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: HAVEN™ Spinal System

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: May 12, 2017

Device Name: HAVEN™ Laminoplasty System
CANOPY® Laminoplasty Fixation System

Common Name: Spinal interlaminal fixation orthosis (NQW)
Classification: Per 21 CFR as follows:
§888.3050 Spinal Interlaminal Fixation Orthosis
Product Code: NQW
Regulatory Class: II, Panel Code: 87

Primary Predicate: CANOPY® Laminoplasty Fixation System (K121732)

Additional Predicates: RELIEVE® Laminoplasty Fixation System (K080664)
Mountaineer Laminoplasty System (K091994)

Reference Device: REVERE® Stabilization System (K133350)

Purpose:
The purpose of this submission is to request clearance for HAVEN™ implants and additional CANOPY® implants, and additional indications for CANOPY®.

Device Description:
The HAVEN™ Laminoplasty System consists of spinal fixation plates for use in Laminoplasty. These implants are composed of titanium or titanium alloy (per ASTM F67, F136, F1295, and F1472). HAVEN™ implants may be used with previously cleared CANOPY®, RELIEVE®, QUARTEX™, ELLIPSE®, PROTEX CT® screws and CANOPY® Spacer.

The CANOPY® Laminoplasty Fixation System consists of spinal fixation plates and screws for use in laminoplasty procedures. CANOPY® implants are inserted through a posterior cervical or thoracic approach, and are available in various sizes and geometric options to fit individual patient anatomy. Fixation plates may be

used with bone graft material. Hinge plates may be used to stabilize a weakened or displaced lamina. Screws are used to attach the plates to bone and are available in a variety of lengths and diameters to fit patient anatomy.

CANOPY® plates and screws are manufactured from titanium or titanium alloy, as specified in ASTM F67, F136, F1295 and F1472. Optional graft chambers are manufactured from radiolucent PEEK as specified in ASTM F2026 and contain tantalum or titanium alloy markers to permit radiographic visualization, per ASTM F67, F136, F560, F1295 or F1472.

Indications for Use:
The HAVEN™ Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The HAVEN™ Laminoplasty System is used to hold bone allograft or autograft material in place in order to prevent the graft from expulsion or impinging the spinal cord.

The CANOPY® Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The CANOPY® Laminoplasty Fixation System is used to hold bone allograft or autograft material in place in order to prevent the graft from expulsion or impinging the spinal cord.

Performance Data:
Performance of the HAVEN™ Laminoplasty System was evaluated in accordance with the “Guidance for Industry and FDA Staff, Guidance for Spinal Systems 510(k)s,” May 3, 2004. Compression, cantilever bending and expulsion testing performed on the HAVEN™ plates demonstrates substantial equivalence to the predicate devices. No additional testing for CANOPY® plates was performed. Bacterial endotoxin testing was also performed.

Technological Characteristics:
The HAVEN™ and additional CANOPY® 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:
The HAVEN™ Laminoplasty System and CANOPY® Laminoplasty Fixation System 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 laminoplasty devices to the predicate devices.