



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

February 3, 2016

Re: K153203
Trade/Device Name: Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 5, 2016
Received: January 6, 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

Indications for Use

510(k) Number (if known)

K153203

Device Name

Navigation Instruments

Indications for Use (Describe)

Globus Navigation Instruments are intended to be used in the preparation and placement of Globus screws (CREO, REVERE, REVOLVE, ELLIPSE and PROTEX CT Stabilization Systems) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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: Navigation Instruments

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory & Clinical Affairs

Date Prepared: January 5, 2016

Device Name: Navigation Instruments

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic Instrument
Product Code: OLO
Regulatory Class: II, Panel Code: 84

Primary Predicate: Medtronic instruments (K143628, K143375, K140454)

Purpose:

The purpose of this submission is to request clearance for the Globus Navigation Instruments for use with the Medtronic StealthStation® System.

Device Description:

Navigation Instruments are nonsterile, reusable instruments including probes, drill bits, drill guides, taps, and drivers that can be operated manually. These instruments are intended to be used with the Medtronic Synergy Spine and Trauma StealthStation® System (v 2.1.0) and are manufactured from stainless steel, as specified in ASTM F899.

Indications for Use:

Globus Navigation Instruments are intended to be used in the preparation and placement of Globus screws (CREO, REVERE, REVOLVE, ELLIPSE and PROTEX CT Stabilization Systems) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Technological Characteristics as Compared to the Predicates:

The Globus Navigation Instruments and the predicate instruments are intended to be used with the Medtronic StealthStation® System to assist the surgeon in locating anatomical structures. These instruments have similar designs, are made from the same materials, and function in the same manner as the predicates. Performance testing shows that the Globus Navigation Instruments are substantially equivalent to the predicate instruments.

Performance Data:

Design validation testing, including rigidity, registration, and accuracy, was conducted to ensure the Navigation Instruments are acceptable for their intended use, to ensure functionality and compatibility with the Medtronic StealthStation®, and to demonstrate substantial equivalence to the predicate instruments. Rigidity testing evaluated the connection between the NavLock Tracker and the instruments. Registration testing was performed to ensure that the instruments can be registered to the StealthStation®. Accuracy testing was completed for comparison to the predicate instruments.

Basis of Substantial Equivalence:

Navigation Instruments 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 devices to the predicate devices. Globus Navigation Instruments are as safe, as effective, and perform equivalent to the predicate devices.