



September 21, 2016

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

Re: K161591

Trade/Device Name: QUARTEX™ Occipito-Cervico-Thoracic Spinal System,
Globus Navigation Instruments

Regulatory Class: Unclassified

Product Code: NKG, KWP, OLO

Dated: September 7, 2016

Received: September 8, 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" (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,

Vincent J. Devlin -S

for

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)
K161591

Device Name
QUARTEX™ Occipito-Cervico-Thoracic Spinal System

Indications for Use (Describe)

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

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:

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

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Indications for Use

510(k) Number (if known)
K161591

Device Name
Globus Navigation Instruments

Indications for Use (Describe)

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws (QUARTEX, 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)

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FOR FDA USE ONLY

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

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510(k) Summary: QUARTEX™ Occipito-Cervico-Thoracic Spinal System and Globus 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 and Clinical Affairs

Date Prepared: September 15, 2016

Device Name: QUARTEX™ Occipito-Cervico-Thoracic Spinal System,
Globus Navigation Instruments

Classification: QUARTEX™ Occipito-Cervico-Thoracic Spinal System
Pre-Amendment Device
Cervical Pedicle Screw Spinal Fixation Orthosis
Product Code: NKG
Regulatory Class: Unclassified

Per 21 CFR as follows:
§888.3050 Spinal Interlaminar Fixation Orthosis
Product Code: KWP
Regulatory Class: II, Panel Code: 87

Globus Navigation Instruments
Per 21 CFR as follows:
§882.4560 Stereotaxic Instrument
Product Code: OLO
Regulatory Class: II; Panel Code: 87

Predicates: QUARTEX™ Occipito-Cervico-Thoracic Spinal System
Primary predicate: ELLIPSE® OCT Spinal System (K150552)
Additional predicates: Synapse OCT System (K142838)
Reference: H-LINK™ Integrated Rod (K073517)
PROTEX CT® (K050391)

Globus Navigation Instruments
Additional predicate: Globus Navigation Instruments (K153203)

Purpose:

The purpose of this submission is to request clearance for QUARTEX™ Occipito-Cervico-Thoracic Spinal System implants and instruments, and Globus Navigation instruments for use with the Medtronic StealthStation® System.

Device Description:

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System consists of 3.5mm-4.0mm jointed, straight and pre-bent rods, tapered rods, polyaxial screws, hooks, locking caps, t-connectors, lateral connectors, parallel connectors, in-line connectors, rod-to-rod connectors, rod extension clamps, QUARTEX™ H-LINK™ Integrated Rod and occipital plates. The implants are composed of titanium alloy (per ASTM F136, F1472, or F1295), stainless steel (per ASTM F138) or cobalt chromium molybdenum alloy (CoCr) (per ASTM F1537).

QUARTEX™ constructs may be connected to stabilization systems including ELLIPSE®, PROTEX® CT, PROTEX® , CREO®, REVERE®, or BEACON® Systems using corresponding connectors.

The QUARTEX™ System include manual surgical instruments manufactured from stainless steel, as specified in ASTM F899. Globus Navigation Instruments are nonsterile, reusable instruments that can be operated manually and are intended to be used with the Medtronic StealthStation® System.

Indications for Use:**QUARTEX™ Occipito-Cervico-Thoracic Spinal System**

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

Globus Navigation Instruments

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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.

Performance Data:

Performance of the QUARTEX™ Occipito-Cervico-Thoracic Spinal System was evaluated in accordance with ASTM F1717, ASTM F2706, and the “Guidance for Industry and FDA Staff, Guidance for Spinal Systems 510(k)s,” May 3, 2004. Performance data demonstrate substantial equivalence to the predicate devices. A comparative analysis was provided for the Globus Navigation Instruments and its predicate device. Bacterial endotoxin testing was also provided.

Basis of Substantial Equivalence:

The QUARTEX™ Occipito-Cervico-Thoracic Spinal System and Globus Navigation Instruments have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The subject devices perform as well as or better than the predicate devices.