Globus Medical Inc.
Jennifer Antonacci
Group Manager, Regulatory Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

August 18, 2021

Re: K211957
Trade/Device Name: QUARTEX™ Occipito-Cervico-Thoracic Spinal System, Globus Navigation Instruments
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP, OLO
Dated: June 23, 2021
Received: June 24, 2021

Dear Jennifer Antonacci:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211957

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
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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211957

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®, PROTEX® CT, and SI-LOK®) 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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510(k) Summary: QUARTEX™ Additional Implants

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

Contact: Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs

Date Prepared: August 17, 2021

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

Classification: QUARTEX™ Occipito-Cervico-Thoracic Spinal System
Per 21 CFR §888.3075 Posterior Cervical Screw System
Product Code: NKG
Regulatory Class: II, Panel Code: 87

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

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

Primary Predicate: QUARTEX™ OCT Spinal System (K161591)

Addtl. Predicates: ELLIPSE® OCT Spinal System (K090565, K110963)
PROTEX® CT OCT Spinal System (K050391)

Reference Device: CREO® Stabilization System (K180210, K124058)

Purpose:
The purpose of this submission is to request clearance for additional QUARTEX™ implants and instruments.

Device Description:
The QUARTEX™ Occipito-Cervico-Thoracic Spinal System includes 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 and screws. The implants are composed of titanium alloy, stainless steel, or cobalt chromium molybdenum (CoCr) alloy.

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

Indications for Use:
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 are intended to be used during the preparation and placement of Globus screws (QUARTEX™, CREO®, REVERE®, REVOLVE®, ELLIPSE®, PROTEX® CT, and SI-LOK®) 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.

Performance Data:
Mechanical testing (static and dynamic compression bending and static interconnection testing) was conducted in accordance with ASTM F1717, ASTM F1798, and the “Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s,” May 3, 2004. Performance data demonstrate substantial equivalence to the predicate devices. Bacterial endotoxin testing (BET) was also conducted in accordance with ANSI/AAMI ST-72:2011.

Technological Characteristics:
Subject 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:
Subject QUARTEX™ 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 of the subject devices to the predicate devices.