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

June 4, 2015

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

Re: K150552
Trade/Device Name: ELLIPSE® and PROTEX® CT Occipito-Cervico-Thoracic Spinal Systems
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: March 16, 2015
Received: March 17, 2015

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 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)*

K150552

Device Name
ELLIPSE® and PROTEX® CT Occipito-Cervico-Thoracic Spinal Systems

Indications for Use *(Describe)*
ELLIPSE® and PROTEX® CT 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)

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.

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510(k) Summary: ELLIPSE® and PROTEX® CT Spinal Systems

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: June 2, 2015

Device Name: ELLIPSE® and PROTEX® CT
Occipito-Cervico-Thoracic Spinal Systems

Classification: Pre-Amendment Device
Cervical Pedicle Screw Spinal Fixation Orthosis
Product Code: NKG
Regulatory Class: Unclassified

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

Primary Predicate: Vertex Reconstruction System (K143471)

Additional Predicates: ELLIPSE® OCT Spinal System (K090565, K110963, K123783)
PROTEX® CT OCT Spinal System (K050391, K081906)
Synapse OCT System (K142838)

Purpose:
The purpose of this submission is to request additional indications for the use of screws in the posterior cervical spine for the ELLIPSE® and PROTEX® CT Occipito-Cervico-Thoracic Spinal Systems.

Device Description:
The ELLIPSE® Occipito-Cervico-Thoracic Spinal System consists of 3.5mm 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 and occipital plates. CAPITOL™ screws and rods are also available as components of the ELLIPSE® system. 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). Mixing of stainless steel implant components with different

materials is not recommended for metallurgical, mechanical and functional reasons.

The PROTEX® CT Occipito-Cervico-Thoracic Spinal System consists of rods, polyaxial screws, hooks, locking caps, t-connectors, lateral connectors, parallel connectors, and occipital clamps. The implants are composed of titanium alloy (per ASTM F136, F1472, or F1295) or stainless steel (per ASTM F138). Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium or titanium alloy implants.

Indications for Use:
ELLIPSE® and PROTEX® CT 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 other occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

Performance Data:
There have been no design changes made to the ELLIPSE® and PROTEX® CT Occipito-Cervico-Thoracic Spinal systems in this submission. The purpose of this 510(k) submission is to obtain clearance for the added indications to use posterior screws in the cervical region of the spine to the ELLIPSE® (K090565, K110963, K123783) and PROTEX® CT (K050391, K081906) Occipito-Cervico-Thoracic Spinal systems. Published literature and mechanical testing per ASTM F1717 (static/dynamic compression bending, static/dynamic torsion) demonstrate that the ELLIPSE® and PROTEX® CT Occipito-Cervico-Thoracic Spinal systems are substantially equivalent.

Basis of Substantial Equivalence:
The ELLIPSE® and PROTEX® CT Occipito-Cervico-Thoracic Spinal systems have the same intended use, similar indications for use, similar technological characteristics and design, same materials and the same principles of operation as the predicate device VERTEX Reconstruction System (K143471).