MAR 1 4 2013

510(k) Summary: ELLIPSE® Additional Implants

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

Contact: Sarah Marie Fitzgerald
Project Manager, Regulatory Affairs

Date Prepared: January 16, 2013

Device Name: ELLIPSE® Occipito-Cervico-Thoracic Spinal System, including CAPITOL™ Implants

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

Predicate(s): ELLIPSE® Occipito-Cervico-Thoracic Spinal System (K090565 & K110963)
PROTEX® CT Cervicothoracic Spinal System (K050391 & K081906)
REVERE® Stabilization System (K061202 & K122226)
Blackstone™ Ascent® Posterior Occipital Cervico-Thoracic System (K080394)

Purpose:
The purpose of this submission is to request clearance for additional screw, locking cap, and rod implants for the ELLIPSE® Occipito-Cervico-Thoracic Spinal System, including CAPITOL™ Implants, which include polyaxial screws with an angled rod seat and curved rods.

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). Due to the risk of galvanic corrosion following implantation, titanium alloy or CoCr implants should not be connected to stainless steel implants.

Indications for Use:
The ELLIPSE® Occipito-Cervico-Thoracic Spinal System is intended to be used in skeletally mature patients as an adjunct to fusion using autograft or allograft, for stabilization of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) for the following conditions: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, atlanto/axial fracture with instability, occipitocervical dislocation, revision of previous cervical spine surgery, and tumors.

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine. Occipital bone screws are limited to occipital fixation; they are not intended for fixation of the posterior cervical spine.

The ELLIPSE® Occipito-Cervico-Thoracic Spinal System 3.5mm rods can also be linked to rod systems ranging in diameter from 3.2mm to 6.5mm, including the PROTEX® CT or PROTEX®, REVERE®, or BEACON® Stabilization Systems, using corresponding connectors.

Performance Data:
Mechanical testing (static and dynamic compression bending, static torsion, and axial gripping capacity) 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.

Conclusions / Basis of Substantial Equivalence:
The ELLIPSE® Additional Implants are similar to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices. The ELLIPSE® Additional Implants are as safe, as effective, and perform as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2013

Globus Medical Incorporated
% Ms. Sarah Marie Fitzgerald
Project Manager, Regulatory Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K123783
Trade/Device Name: ELLIPSE® Occipito-Cervico-Thoracic Spinal System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: January 16, 2013
Received: January 17, 2013

Dear Ms. Fitzgerald:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K123783

Device Name: ELLIPSE® Occipito-Cervico-Thoracic Spinal System

Indications:

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Prescription Use __X____ OR Over-The-Counter Use___
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123783