

JUN 14 2012

K113395

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510(k) Summary: REVERE® 4.5 Stabilization System

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

Contact: Sarah Marie Fitzgerald
Project Manager, Regulatory Affairs

Date Prepared: May 4, 2012

Device Name: REVERE® 4.5 Stabilization System

Classification: Per 21 CFR as follows:
§888.3050 Spinal Interlaminar Fixation Orthosis
§888.3060 Spinal Intervertebral Body Fixation Orthosis
§888.3070 Pedicle Screw Spinal System
§888.3070 Spondylolisthesis Spinal Fixation Device System
§888.3070 Pedicle Screw Spinal System, Adolescent
Idiopathic Scoliosis
Product Codes MNH, MNI, KWQ, KWP, NKB, OSH
Regulatory Class II and III, Panel Code 87.

Predicate(s): REVERE® Stabilization System K061202, K091782 &
K100788
Medtronic CD Horizon® Spinal System K091445 & K102807
Synthes Small Stature USS K994121 & K103287

Purpose:

The purpose of this submission is to request clearance of the REVERE® 4.5 Stabilization System for skeletally mature and pediatric indications for use.

Device Description:

The REVERE® 4.5 Stabilization System consists of rods, hooks, monoaxial screws, Uniplanar screws, polyaxial screws, reduction screws, locking caps, t-connectors, head offset connectors, trans-iliac connectors, staples, and associated manual surgical instruments. Screws are available in a variety of sizes to accommodate individual patient anatomy. REVERE® 4.5 implants mate with 4.5mm diameter rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws, hooks, and t-connectors are intended for posterior use only. Staples intended for anterior use only. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws or hooks to the rod and trans iliac connectors.

The most common use of this screw, hook, and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws and/or lamina, pedicle or transverse process hooks.

The most common use of this screw, hook, and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via monoaxial screws through an appropriate size staple.

Screws and hooks attach to the rods using a locking cap with an inner set screw. The size and number of screws are dependent on the length and location of the rod. Screws are inserted into a pedicle of the thoracolumbar and/or sacral spine. The type and number of hooks are also dependent on the location in the spine needing correction and/or stabilization. Hooks are attached to the laminae, pedicles, or transverse process of the posterior spine.

T-connectors are modular components designed to connect the two rods of a construct and act as a structural cross member. The rod-clamping set screws secure the t-connectors to the rods. Additional set screws secure the adjustable cross members at the desired length. REVERE[®] 4.5 t-connectors may only be used with 4.5mm diameter rods. Additional connectors may be used to connect two rods, and are also secured using set screws.

REVERE 4.5 Stabilization System S-rods and unit rods are specifically excluded for use in adolescent idiopathic scoliosis patients.

The rods are composed of titanium alloy, commercially pure titanium, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F67, F1537 and F138. All other REVERE[®] 4.5 implants are composed of titanium alloy or stainless steel, as specified in ASTM F136, F1295, F67 and F138. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy, or cobalt chromium-molybdenum alloy implants.

Indications for Use:

The REVERE[®] 4.5 Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and pediatric patients. These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis).

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the REVERE[®] 4.5 Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The REVERE[®] 4.5 Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the REVERE[®] 4.5 Stabilization System rods may be connected to the REVERE[®] Stabilization System (5.5mm or 6.35mm rod) or ELLIPSE[®] Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. Refer to the REVERE[®] or ELLIPSE[®] system package insert for instructions and indications of use.

Performance Data:

Mechanical testing (static and dynamic compression, and static torsional) was conducted in accordance with ASTM F1717 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 device.

Basis of Substantial Equivalence:

The REVERE[®] 4.5 Stabilization System implants are similar to the predicate REVERE[®] Stabilization System (K061202, K091782 & K100788), Medtronic CD Horizon[®] Spinal System (K091445 & K102807) and Synthes Small Stature USS (K994121 & K103287) implants with respect to technical characteristics, performance, and intended use. Substantial equivalence determination of the subject system to the predicate devices is based on a dimensional and engineering analysis as well as preclinical testing. The information provided within this premarket notification supports substantial equivalence to the predicate device(s).



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

June 27, 2013

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

Re: K113395

Trade/Device Name: REVERE® 4.5 Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, OSH, KWP, KWQ, MNH, MNI
Dated: May 9, 2012
Received: May 10, 2012

Dear Ms. Fitzgerald:

This letter corrects our substantially equivalent letter of June 14, 2012.

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 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>. 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

For

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: K113395

Device Name: REVERE® 4.5 Stabilization System

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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)

Cynthia Keith
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113395