K073439

510(k) SUMMARY: TRANSITION™ STABILIZATION SYSTEM

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
(610) 415-9000

Contact: Kelly J. Baker, Ph.D
Director, Clinical Affairs & Regulatory

FEB 20 2009

Device Name: TRANSITION™ Stabilization System

Classification: Product Code NQP. Class II.
21 CFR §888.3070 Pedicle Screw Spinal System

Predicate(s): REVERE (K061202), Dynesys (K031511)

Device Description:
The TRANSITION™ Stabilization System implants include pedicle screws and implant assemblies which are provided pre-assembled or can be assembled intraoperatively.

TRANSITION™ pedicle screws are coated with hydroxyapatite (HA). Either TRANSITION™ HA coated pedicle screws or specified REVERE® pedicle screws may be used in conjunction with the implant assemblies. Specifically, REVERE® polyaxial (solid, cannulated and dual outer diameter) screws and monoaxial screws 6.5mm diameter and larger, and 35mm length and larger, may be used with the TRANSITION™ implant assemblies.

Implant assemblies consist of a polyethylene terepthalate (PET) cord, polycarbonate urethane (PCU) spacers and bumpers, and titanium alloy spools, end spools and set screw ends. The cord passes through the entire implant such that the spools are positioned to sit within the screw heads and the spacer sits between the spools. The end spool includes one end of the secured cord. The bumper followed by a set screw end is positioned at the other end of the cord.

Implant assemblies are available in single or multi-level configurations. REVERE® locking caps with inner set screws are used to rigidly connect the pedicle screws to the implant assemblies.

TRANSITION™ implants are available in a variety of sizes to accommodate varied patient anatomy.

TRANSITION™ implants are manufactured from titanium alloy Ti6Al4V (ASTM F136) or Ti6Al7Nb (ASTM F1295), polyethylene terepthalate (PET), and/or polycarbonate urethane (PCU). Titanium alloy TRANSITION™ screws are hydroxyapatite (HA) coated (ASTM F1185).

K073439

Intended Use/Indications for Use:
The TRANSITION™ Stabilization System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine in skeletally mature patients: degenerative spondylolisthesis with objective evidence of neurologic impairment, kyphosis, and failed previous fusion (pseudoarthrosis).

In addition, the TRANSITION™ Stabilization System is indicated for use in patients: who are receiving fusions with autogenous graft only; who are having the device fixed or attached to the lumbar or sacral spine; and who are having the device removed after the development of a solid fusion mass.

TRANSITION™ is only indicated for use when fusion with autogenous bone graft is being performed at all instrumented levels.

Basis for Substantial Equivalence:
The TRANSITION™ Stabilization System has been found to be substantially equivalent to the previously cleared predicate devices in terms of indications for use, design, function, and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2009

Globus Medical Inc.
% Kelly J. Baker, PhD
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K073439
Trade/Device Name: TRANSITION™ Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: II
Product Code: NQP
Dated: November 24, 2008
Received: November 25, 2008

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device has not been established for the intended use of spinal stabilization without fusion. This device is only intended to be used when fusion with autogenous bone graft is being performed at all instrumented levels.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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); 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 information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K073439

Device Name: TRANSITION™ Stabilization System

Indications:

The TRANSITION™ Stabilization System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine in skeletally mature patients: degenerative spondylolisthesis with objective evidence of neurologic impairment, kyphosis, and failed previous fusion (pseudoarthrosis).

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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)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073439