III. 510(K) Summary

K040284

MAR 23 2004

SUBMITTED BY:

Globus Medical Inc.
303 Schell Lane
Phoenixville, PA 19460
(610) 415-9000 x218
Contact: Kelly J. Baker

DEVICE NAME:

Sustain Radiolucent Spacer

CLASSIFICATION:

Per CFR 21 §888.3060: Implant, fixation, spinal intervertebral body fixation orthosis devices. Class II.
The Product Code is MQP. The Panel Code is 87.

PREDICATE DEVICES:

Globus Sustain Spacer K031302, SE date June 27, 2003

Other legally marketed devices:
Synthes Vertebral Spacer K011037, SE date July 1, 2002
Medtronic Sofamor Danek Verte-Stack K031780, SE date July 30, 2003
Signus Tetris K031757, SE date July 30, 2003 (*Special 510(k)*)

DEVICE DESCRIPTION:

The Sustain Radiolucent Spacer is a vertebral body replacement device used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The system is comprised of spacers of various fixed heights and footprints to fit the anatomical needs of a wide variety of patients. Each spacer has an axial hole to allow grafting material to be packed inside of the spacer. Protrusions on the superior and inferior surfaces of each device will grip the endplates of the adjacent vertebrae to resist expulsion.

The Sustain Radiolucent Spacer devices are made from radiolucent polymer and titanium alloy as specified in ASTM F2026 and F136.

INTENDED USE:

The Sustain Radiolucent Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture).

The Sustain Radiolucent Spacer is intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material.

The Sustain Radiolucent Spacer is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

PERFORMANCE DATA:

Mechanical testing in accordance with the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", September 27, 2000 was presented.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Sustain Radiolucent Spacer implants are similar to the predicate vertebral body replacement device, Globus Sustain Spacer (K031302), with respect to functional design, indications for use, principles of operation, and performance. The material is changed to a radiolucent polymer that is being used in other legally marketed devices within the same classification regulation for the same intended use as the Sustain Spacer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2004

Kelly J. Baker, Ph.D.
Project Manager, Quality Assurance and Regulatory Affairs
Globus Medical, Inc.
303 Schell Lane
Phoenixville, PA 19460

Re: K040284
Trade/Device Name: Sustain Radiolucent Spacer
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: March 3, 2004
Received: March 8, 2004

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.

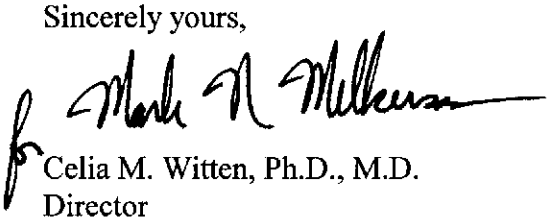
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Indications for Use Statement

510(k) Number: K040284

Device Name: Sustain Radiolucent Spacer

Indications:

The Sustain Radiolucent Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The Sustain Radiolucent Spacer is intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material.

The Sustain Radiolucent Spacer is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

for Mark N Melkerson

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

510(k) Number K040284