Section 5 - 510(k) Summary

Submitter Information

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DEC 26 2006

Date Prepared
October 31, 2006

Product Name
obelisc™ Vertebral Body Replacement

Predicate Device
This device is substantially equivalent to the following legally marketed devices:

510(k) Reference	Description	Submitted By
K050850	XPAND Corpectomy Spacer	Globus Medical, Inc.
K012254	VBR™ Vertebral Body Replacement Device	Osteotech, Inc.

Product Description

The obelisc™ Vertebral Body Replacement device is used for the bridging of substance defects in the anterior human thoracic and lumbar spine.

The defect is bridged by distraction of the implant and the vertebral column is straightened. Via a bevel gear drive unit, the necessary height of the implant can be adjusted exactly and fixed in situ. The height can be adjusted via a bevel gear drive unit, with pins to prevent overdistraction. The adjusted height is fixed in position by means of a locking screw. Spikes at the end pieces improve the anchoring of the implant on the end plates of the vertebral bodies.

Bone graft material can be placed around the obelisc™ Vertebral Body Replacement as needed.

The obelisc™ Vertebral Body Replacement consists of a center piece and two corresponding straight or angled end pieces. The standard diameter of the center pieces is 20 mm. One end has already been produced with a 0° end piece with Ø 20 mm. The end pieces are available in three diameters (20 mm, 24 mm, 26 mm) and with different angles (0°, 5°, 10°). One oval end piece (26 x 30 mm) with an angle of 15° is available. The center piece defines the minimum and maximum expansion height. The distraction heights range from 20 to 132 mm.

Table: obelisc™ Vertebral Body Replacement implant product list

Implants	Height	Product number
obelisc™ center piece, Ø 20 mm	20 – 28 mm	CS 2920-20
	25 – 37 mm	CS 2920-25
	32 – 47 mm	CS 2920-32
	40 – 62 mm	CS 2920-40
	53 – 87 mm	CS 2920-53
	76 – 132 mm	CS 2920-76
obelisc™ end piece, Ø 20 mm	0°	CS 2921-00
	5°	CS 2921-05
	10°	CS 2921-10
obelisc™ end piece, Ø 24 mm	0°	CS 2922-00
	5°	CS 2922-05
	10°	CS 2922-10
obelisc™ end piece, Ø 26 mm	0°	CS 2923-00
	5°	CS 2923-05
	10°	CS 2923-10
obelisc™ end piece, oval,, 32 x 26 mm	15°	CS 2924-15
obelisc™ locking screw		CS 2901

The implant components of this system are made from alloyed titanium according to ISO 5832-3:2000 and ASTM F-136-02a.

Intended Use

Vertebral body replacement intended for use during open surgical procedures in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (e.g., fracture). The obelisc™ Vertebral Body Replacement is intended to be used with supplemental internal spinal fixation systems that have been labeled for use in the thoracic and lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The use of bone grafting material with the obelisc™ Vertebral Body Replacement is optional.

Substantial Equivalence

This device is substantially equivalent to the following legally marketed devices:

510(k) Reference	Description	Submitted By
K050850	XPAND Corpectomy Spacer	Globus Medical, Inc.
K012254	VBR™ Vertebral Body Replacement Device	Osteotech, Inc.

A comparison of devices is provided below (table follows on next page):

	obelisc™ Vertebral Body Replacement	XPAND	VBR™
Intended use	Vertebral body replacement; for use with supplemental spinal fixation systems	Vertebral body replacement; for use with supplemental spinal fixation systems	Vertebral body replacement; for use with supplemental spinal fixation systems
Anatomical sites	Thoracic and lumbar spine (T1-L5)	Thoracic and lumbar spine (T1-L5)	Thoracic and lumbar spine (T1-L5)
Material	Titanium alloy	Titanium alloy	Titanium alloy
Bone graft material	Narrow build to permit external bone graft material; may also be filled	Axial hole for bone graft material	Hollow core for bone graft material
Diameter	20-30mm	Various fixed heights & footprints	12-16mm, 20-28mm
Distraction length	20-132mm	Various fixed heights & footprints	10-130mm
Exact height adjustment in situ	Continuous in-situ distraction	Continuous in-situ distraction	Continuous in-situ distraction
Contact areas	Large contact areas. Additional application of bone graft outside the implant may enhance the fusion mass.	N/A	Large contact areas. Additional application of bone graft outside the implant may enhance the fusion mass.

Summary of Testing

Mechanical testing was performed in accordance with ASTM F 2077 – 00 (Test Methods for Intervertebral Body Fusion Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ulrich GmbH & Co. KG
% Emergo Group, Inc.
Mr. Ian P. Gordon
Senior Vice President
2454 McMullen Booth Road, Suite 427
Clearwater, Florida 33759

DEC 26 2006

Re: K060416
Trade/Device Name: obelisc™ Vertebral Body Replacement
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: October 31, 2006
Received: November 1, 2006

Dear Mr. Gordon:

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.

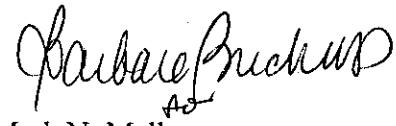
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060416

Device Name: obelisc™ Vertebral Body Replacement

Indications for Use:

Vertebral body replacement intended for use during open surgical procedures in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (e.g., fracture). The obelisc™ Vertebral Body Replacement is intended to be used with supplemental internal spinal fixation systems that have been labeled for use in the thoracic and lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The use of bone grafting material with the obelisc™ Vertebral Body Replacement is optional.

Prescription Use ___XX____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruchman

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

510(k) Number K060416