K051781

1 of 2

DEC 16 2005

510(k) Summary
GraftCage™ TLX

Submitted by	Address	Telephone	Contact Person
Osteotech, Inc.	51 James Way Eatontown, New Jersey 07724	(800) 537-9842 x 6324	Christopher Talbot Dir. Regulatory Affairs
DATE June 20, 2005	**Subject Device**		**Predicate Devices**
Trade Name	GraftCage TLX		• Synthes Spine's Vertebral Spacer-TR, K011037, cleared July 1, 2002; • Interpore Cross's GEO Structure, K010530, cleared August 3, 2001; and • Stryker Spine's AVS TL Spacer, K042571 cleared February 11, 2005.
Common Name	Vertebral Body Replacement Device		
Classification Name	Spinal Intervertebral Body Fixation Orthosis		

Device Description:

The GraftCage TLX is a device designed to replace a thoracic or lumbar vertebral body and to support axial compression loads following vertebrectomy for the treatment of spinal tumors and in cases of spinal trauma/fracture. The GraftCage TLX is made from implantable PEEK (polyetheretherketone) polymer.

The GraftCage TLX is rectangular -to- oval in shape, with its anterior aspect slightly convex and posterior aspect slight concave. One central (axial) fenestration and two fenestrations on each anterior and posterior aspect provide locations for the addition of bone grafting material. The superior and inferior aspects have ridges that resist expulsion and /or migration after implantation. The device is non-lordotic (0°) i.e., parallel. The lateral aspects are tapered, or bulleted, for ease of insertion.

Two threaded holes, one at each lateral aspect, interface with the insertion tool. The insertion tool is a shaft attached to a handle. The shaft has a threaded end that matches both threaded holes on the GraftCage TLX and allows the surgeon to hold the GraftCage TLX while implanting it into the patient. Each threaded hole is at a different angle relative to the long axis of the implant. The different angles allow the surgeon to choose the best surgical approach depending upon the specific clinical situation.

Intended Use:

The GraftCage™ TLX is a vertebral body replacement device intended to replace a collapsed, damaged, or unstable vertebral body in the thoracic or lumbar spine (T1-L5). The GraftCage TLX is indicated for a partial or total vertebrectomy for cases of tumor or trauma (i.e., fracture). The GraftCage TLX is intended to achieve anterior decompression of the spinal cord and neural tissues and to restore the height of a collapsed vertebral body.

The GraftCage TLX is intended for use with supplemental internal spinal fixation systems that are cleared by FDA for use in the thoracic and lumbar spine. These systems include posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems. The use of bone grafting material with the GraftCage TLX is optional.

Comparison to Predicate:

The GraftCage TLX claims substantial equivalence to:

1) Synthes Spine's Vertebral Spacer-TR, K011037, cleared July 1, 2002;
2) Interpore Cross's GEO Structure, K010530 cleared August 3, 2001; and
3) Stryker Spine's AVS TL Spacer, K042571 cleared February 11, 2005.

This claim of substantial equivalence is intended to reflect FDA's definition of substantial equivalence as defined by 21 CFR Part 807, Subpart E and is not intended to reflect a claim of substantial equivalence in terms of intellectual property.

The GraftCage TLX and the predicate devices have the same intended use and similar technological characteristics. Performance data demonstrates that the GraftCage TLX meets or exceeds functional requirements for a vertebral body replacement device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Mr. Christopher Talbot
Director, Regulatory Affairs
Osteotech Incorporated
51 James Way
Eatontown, New Jersey 07724

Re: K051781
Trade Name: GraftCage™ TLX VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: December 8, 2005
Received: December 9, 2005

Dear Mr. Talbot:

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.

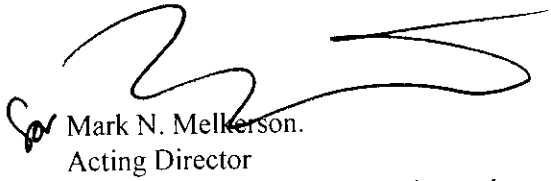
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): K051781

DEVICE NAME: GraftCage TLX

INDICATIONS FOR USE:

The GraftCage™ TLX is a vertebral body replacement device intended to replace a collapsed, damaged, or unstable vertebral body in the thoracic or lumbar spine (T1-L5). The Graftcage TLX is indicated for a partial or total vertebrectomy for cases of tumor or trauma (i.e., fracture). The GraftCage TLX is intended to achieve anterior decompression of the spinal cord and neural tissues and to restore the height of a collapsed vertebral body.

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The use of bone grafting material with the GraftCage TLX is optional.

Prescription Use ✓ **OR** **Over-The-Counter-Use**____
(Per 21 CFR 801.109)

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

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

510(k) Number K051781