JUN 2 9 2007

Atlas Spine, Inc.
Special 510(k) Premarket Notification: Atlas Spine Vertebral Body Replacement K071497

510(k) SUMMARY

Manufacturer:	Atlas Spine, Inc.
Address:	1555 Jupiter Park Drive, Suite #4 Jupiter, FL 33458
Telephone:	561-741-1108
Fax:	561-741-1870
Official Correspondent:	Jeannette G. Dailey
Title:	VP Regulatory Affairs
Telephone:	561-354-4319
Device Classification Name:	Spinal intervertebral body fixation orthosis
Trade/Proprietary Name:	Atlas Spine Vertebral Body Replacement
Common Name:	Spinal vertebral body replacement device
Classification:	Class II per 21 CFR §888.3060
Product Code:	MQP
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Device:	Atlas Spine Vertebral Body Replacement K063464

Intended Use:

The Atlas Spine Vertebral Body Replacement (VBR) is intended for use in the thoracolumbar spine (T1-L5) for partial or complete replacement (i.e., vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Atlas Spine VBR is also indicated for treating fractures of the thoracic and lumbar spine.

The Atlas Spine VBR is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The interior of the Atlas Spine VBR can be packed with bone. This device is intended to be used with supplemental spinal fixation systems that have been cleared 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).

Device Description:

The Atlas Spine VBR is generally rectangular in shape with anterior and posterior walls that are concentric arcs. The device is available in various sizes with an anterior height ranging from 10mm to 18mm and anterior width of 28mm while providing 0 or 5 degrees of lordosis. The posterior aspect is tapered, or bulleted, for ease of insertion. All devices are 20.0mm in length. The device design includes four radiopaque markers that allow postoperative radiographic confirmation of the device position and orientation.

Equivalence to Marketed Product

Atlas Spine, Inc. has submitted information to demonstrate that, for the purpose of FDA's regulation of medical devices, the Atlas Spine VBR is substantially equivalent in indications and design principles to the predicate devices that have been determined by FDA to be substantially equivalent to preamendment devices.

The intended use, design, materials and functional characteristics of the Atlas Spine VBR and the predicate devices are substantially the same. Each system is intended to be used to provide support after resection or removal of a damaged, collapsed, or unstable vertebral body due to tumor, fracture, or other disease. The subject device and predicate devices are placed within the area of removed or resected spine and are functionally complemented by supplemental internal fixation. The subject device and the predicate devices are intended to be used with bone graft. The Atlas Spine VBR and the predicate devices are made from implantable PEEK [polyetheretherketone] polymer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

Atlas Spine, Inc.
% Mrs. Jeannette Dailey
Vice President, Regulatory Affairs
1555 Jupiter Park Drive, Suite 4
Jupiter, Florida 33458

Re: K071497
Trade/Device Name: Atlas Spine Vertebral Body Replacement
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: May 30, 2007
Received: May 31, 2007

Dear Mrs. Dailey:

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) 2760-0120. 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

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

Enclosure

Atlas Spine, Inc.
Special 510(k) Premarket Notification: Atlas Spine Vertebral Body Replacement

Indications for Use

510(k) Number (if known): _____

Device Name: Atlas Spine Vertebral Body Replacement

Indications for Use:

The Atlas Spine Vertebral Body Replacement (VBR) is intended for use in the thoracolumbar spine (T1-L5) for partial or complete replacement (i.e., vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Atlas Spine VBR is also indicated for treating fractures of the thoracic and lumbar spine.

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Prescription Use ___X____ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K031497

(Posted November 13, 2003)