K063205

# 510(k) Summary

FEB 26 2007

## Atlas Spine

## Atlas Spine Vertebral Body Replacement

ADMINISTRATIVE INFORMATION

| | |
|---|---|
| Manufacturer Name: | Atlas Spine, Inc.<br>1555 Jupiter Park Dr., #4<br>Jupiter, FL 33458<br>Telephone (561) 741-1108<br>Fax (561) 741-1870 |
| Official Contact: | Jeannette G. Dailey |
| Representative/Consultant: | Floyd G. Larson<br>PaxMed International, LLC<br>11234 El Camino Real, Suite 200<br>San Diego, CA 92130<br>Telephone (858) 792-1235<br>Fax (858) 792-1236 |

DEVICE NAME

| | |
|---|---|
| Classification Names: | Spinal intervertebral body fixation orthosis |
| Trade/Proprietary Name: | Atlas Spine Vertebral Body Replacement |
| Common Name: | Spinal vertebral body replacement device |

DEVICE CLASSIFICATION

FDA has classified spinal intervertebral body fixation orthoses as Class II devices (21CFR 888.3060). The product code for spinal vertebral body replacement device is MQP. These devices are reviewed by the Orthopedic Spine Devices Branch.

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

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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. The device must be used with supplemental internal fixation systems cleared for the conditions listed above (i.e., tumor or trauma of T1-L5).

DEVICE DESCRIPTION

The Atlas Spine VBR is a rectangular, radiolucent vertebral body replacement device designed to replace, in whole or in part, a thoracic or lumber vertebral body after complete or partial vertebrectomy.

The device design includes 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 purposes of FDA's regulation of medical devices, the Atlas Spine VBR is substantially equivalent in indications and design principles to 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. The height, width, length, and lordotic angle of Atlas Spine VBR are within the ranges available for one or more of the predicate devices. 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 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

Atlas Spine Inc.
% Ms. Jeannette G. Dailey
Vice President, Regulatory Affairs
1555 Jupiter Park Dr., Suite #4
Jupiter, Florida 33458

FEB 26 2007

Re: K063205
Trade/Device Name: Atlas Spine Vertebral Body Replacement
Regulation Number: 21 CFR 888.3060
Regulation Name: spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: January 19, 2007
Received: January 22, 2007

Dear Ms. 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.

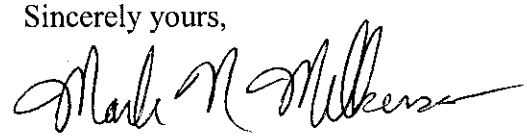
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 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 (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): K063205

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

**510(k) Number** K063205