AUG 10 2010

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:	Vice President Regulatory Affairs & Quality Assurance
Telephone:	561-354-4319
Date Prepared:	June 4, 2010
Device Classification:	Intervertebral body fusion device Class II per 21 CFR §888.3080 Product Code: MAX
Trade/Proprietary Name:	Atlas Spine Pivoting System
Common Names:	Intervertebral Body Fusion Device [IBFD]
Predicate Device:	Novel® Spinal Spacer System Alphatec Spinal, Inc. K080699 Atlas Spine Spacer Atlas Spine, Inc. K091406 Pivotec Lumbar Interbody Fusion Device Captiva Spine, Inc. K092017

Device Description:

The Atlas Spine Pivoting System is an intervertebral body fusion device for use with autogenous bone graft in the intervertebral disc space to stabilize spinal segments and promote fusion.

The Atlas Spine Pivoting System consists of an implant manufactured from PEEK-Optima and insertion tools. The PEEK-Optima implant is crescent-shaped and radiolucent. The implant design includes three (3) radiopaque, tantalum markers, which allow postoperative radiographic confirmation of the device position and orientation. The design also includes two (2) titanium alloy pins which secure the implant to an

insertion tool for placement and deployment. The Atlas Spine Pivoting System is provided in various configurations and heights; containing hollow core to receive bone autograft.

Intended Use:

The Atlas Spine Pivoting System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The Atlas Spine Pivoting System is to be used with a supplemental fixation system and autogenous bone graft.

Performance Data

Pre-clinical, mechanical testing was performed on the Atlas Spine Pivoting System. Testing consisted of static testing in a load to failure mode in axial compression; static testing in expulsion; static testing in subsidence; and dynamic axial compression testing to estimate the maximum run out load. Testing was performed in accordance with ASTM F-2077 and ASTM F-2267. Data have been submitted to characterize the performance of the Atlas Spine Pivoting System.

Discussion of the Technological Characteristics

The intended use, design, materials and functional characteristics of the Atlas Spine Pivoting System and the predicate devices are substantially the same. The height, width, length and lordotic angles of the Atlas Spine Pivoting implant are within the ranges available for the predicate devices. The Atlas Spine Pivoting implant and the predicate devices consist of a single piece that is made from implantable PEEK polymer. The Atlas Spine Pivoting implant, the Novel Spinal Spacer and the Pivotec implant are similarly "crescent" shaped. Each system is intended to restore the biomechanical integrity of the anterior, middle and posterior spinal column. The Atlas Spine Pivoting implant and the predicate devices are placed within the area of removed or resected spine and are functionally complemented by supplemental internal fixation. Manipulation of the Atlas Spine Pivoting implant, the Novel Spinal Spacer and the Pivotec implant is achieved by a unique tool. The Atlas Spine Pivoting implant and the predicate devices are intended to be used with bone graft.

Conclusion

Provided documentation demonstrates that the Atlas Spine Pivoting System is substantially equivalent to the aforementioned predicate devices. This conclusion is based on the devices' similarities in indications for use, design, function, materials and mechanical function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

AUG 10 2010

Re: K100743
Trade/Device Name: Atlas Spine Pivoting System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 26, 2010
Received: July 27, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

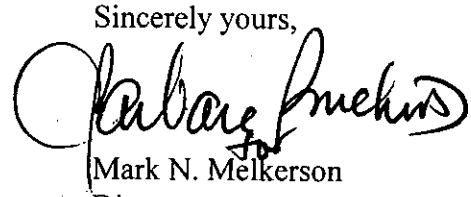
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100743

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Device Name: Atlas Spine Pivoting System

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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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100743

(Posted November 13, 2003)