

K112759

OCT 18 2011

Atlas Spine, Inc.

Special 510(k) Premarket Notification: Atlas Spine Pedicle Screw System

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**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

Establishment Reg. No. 3003855635

Official Correspondent: Thomas G. Smith  
Title: Manager, Regulatory Affairs & Quality Assurance  
Telephone: 561-354-4318

Date Prepared: September 19, 2011

Device Classification  
Name: Spinal pedicle fixation orthosis

Trade/Proprietary Name: Apelo™ Pedicle Screw System

Common Name: Pedicle screw spinal system

Classification: Class III per 21 CFR §888.3070

Product Code: MNI, MNH, and NKB

Classification Panel: Orthopedic and Rehabilitation Devices Panel

Predicate Devices: Apelo™ Pedicle Screw System  
Atlas Spine, Inc.  
K072426, K110842

Coral™ Spinal System  
Theken Spine, LLC  
K041592, K081414

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**Intended Use:**

The Apelo™ Pedicle Screw System is intended for noncervical pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

**Device Description:**

The subject of this submission is the design of Fixed Length Cross Connectors for the Apelo™ Pedicle Screw System and additional smaller sizes, 20mm through and including 42mm. The Atlas Spine Fixed Length Cross Connectors will provide surgeons additional smaller sizes from which to choose based on the patients' anatomies. The Atlas Spine Fixed Length Cross Connectors will be manufactured from medical grade titanium alloy, Ti-6Al-4V (ELI), in accordance with ASTM F-136.

**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 Fixed Length Cross Connectors is substantially equivalent in the intended use, design, materials and functional characteristics compared to the predicate devices.

The subject device similarities include:

- The same indications for use
- The same operating principle
- The same raw materials
- Similar manufacturing environments
- The same packaging configurations
- The same sterilization process
- Implanted using the same surgical techniques and similar equipment types

**Conclusion**

Provided documentation demonstrates that the Atlas Spine Fixed Length Cross Connectors 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.

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Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -W066-G609  
Silver Spring, MD 20993-0002

Atlas Spine, Inc.  
% Mr. Thomas Smith  
Manager, Regulatory Affairs & Quality Assurance  
1555 Jupiter Park Drive, Suite 4  
Jupiter, Florida 33458

OCT 18 2011

Re: K112759  
Trade/Device Name: Apelo Pedicle Screw System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class III  
Product Code: NKB, MNI, MNH  
Dated: September 19, 2011  
Received: September 22, 2011

Dear Mr. Smith:

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

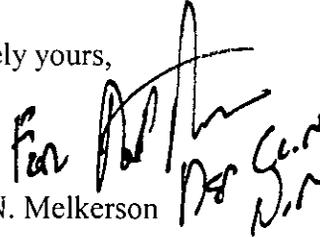
Page 2 - Mr. Thomas Smith

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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style and is positioned above the typed name and title.

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

Enclosure

Atlas Spine, Inc.

Special 510(k) Premarket Notification: Atlas Spine Pedicle Screw System

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## Indications for Use

510(k) Number (if known): K112759

Device Name: Apelo™ Pedicle Screw System

### Indications for Use:

The Apelo™ Pedicle Screw System is intended for noncervical pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use  
(21 CFR 801 Subpart C)

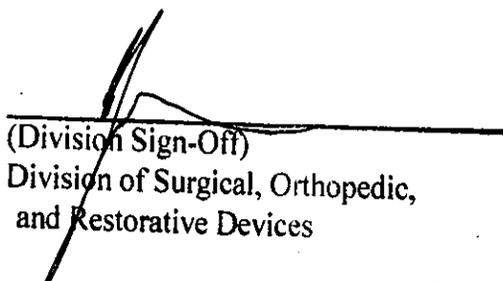
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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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*(Posted November 13, 2003)*

  
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(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number   K112759  

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