

10.0 510(k) Summary**1. Sponsor**

FEB - 2 2010

Spinal Edge LLC
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Rockville, MD 20805

Primary Contact: Ravi Sharma PhD
Telephone: 1- 866-915-9468

Date Prepared: August 3, 2009

2. ATLAS Intervertebral Body Cage:

Proprietary Name: *ATLAS Intervertebral Body Cage*
Common/Usual Name: *ATLAS Intervertebral Body Cage*
Classification Name: *ATLAS Intervertebral Body Cage*
(21 CFR 888.3060), Class II Product Code MQP
and (21 CFR 888.3080), Class II Product Code
MAX

3. Predicate Devices

K060916 – Atlas Spinal Cage
K083815 – Lanx Fusion System
K990148 – Stackable Cage System

4. Device Description

This submission is intended to seek clearance for a product line extension to the *ATLAS Spinal Cage VBR*. The extension includes the addition of 8mm, 10mm, 12mm, 14mm, and 16mm cages to the current offering. Additionally adding the product code MAX for Intervertebral body fusion devices CFR 21 888.3080.

The Spinal Edge *ATLAS Intervertebral Body Cage* is an Intervertebral Body Cage device used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The system is comprised of spacers of various fixed heights and footprints to fit the anatomical needs of a wide variety of patients. Each cage has an axial hole to allow grafting material to be packed inside. Protrusions on the superior and inferior surfaces of the device will grip the cortical endplates of the adjacent vertebrae and resist expulsion. The Spinal Edge *ATLAS Intervertebral Body Cage* components are available in titanium alloy conforming to ASTM F-136 specifications.

5. Intended Use

When used as vertebral body replacement, the *ATLAS Intervertebral Body Cage* is indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma. The *ATLAS Intervertebral Body Cage* is intended to be used with supplemental fixation systems that have been labeled 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) the interior spacer may be packed with bone grafting material. The *ATLAS Intervertebral Body Cage* has been designed to provide anterior column support even in the absence of fusion for a prolonged period of time.

When used as a lumbar intervertebral body fusion device the *ATLAS Intervertebral Body Cage* is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature individuals with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 to S1. DDD is defined and discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have six months of non-operative treatment. These DDD patients may have had previous non-fusion spinal surgery at the involved spinal level(s). The *ATLAS Intervertebral Body Cage* is implanted via an anterior or posterior approach and is combined with supplemental fixation.

For either intended use, the *ATLAS Intervertebral Body Cage* must be used with supplemental internal fixation.

6. Technological Characteristics and Substantial Equivalent

The Spinal Edge *ATLAS Intervertebral Body Cage* devices being added to the product line have the same indications for use, operating principles and are made of the same materials as the predicate devices.

Representative samples of the *ATLAS Intervertebral Body Cage* device underwent testing to demonstrate comparable function and performance characteristics its predicate devices. The additional device sizes in this submission do not introduce any new questions of safety and effectiveness. Mechanical testing and engineering analysis of the results demonstrated comparable mechanical properties to the predicate device.

7. Performance Testing

Performance testing was completed using the largest size *ATLAS Intervertebral Body Cage* (17mm). The devices were tested in accordance with ASTM F2267-04, "Standard Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression" and ASTM F2077-03 "Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Model".



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Spinal Edge, LLC
% CHS Business Associates, LLC
Ms. Christina Vacca
President
33650 Reserve Way
Avon, Ohio 44011

FEB - 2 2010

Re: K092774

Trade/Device Name: ATLAS Intervertebral Body Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: January 12, 2010
Received: January 19, 2010

Dear Ms. Vacca:

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

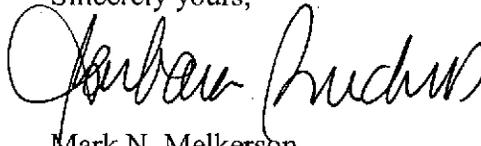
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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing 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/ucml15809.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" (21 CFR 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

9.0 Indications for Use Statement

510(k) Number (if Known): K092774

Indications for Use:

When used as vertebral body replacement, the *ATLAS Intervertebral Body Cage* is indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma. The *ATLAS Intervertebral Body Cage* is intended to be used with supplemental fixation systems that have been labeled 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) the interior spacer may be packed with bone grafting material. The *ATLAS Intervertebral Body Cage* has been designed to provide anterior column support even in the absence of fusion for a prolonged period of time.

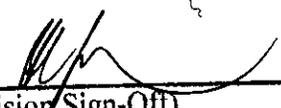
When used as a lumbar intervertebral body fusion device the *ATLAS Intervertebral Body Cage* is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature individuals with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 to S1. DDD is defined and discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have six months of non-operative treatment. These DDD patients may have had previous non-fusion spinal surgery at the involved spinal level(s). The *ATLAS Intervertebral Body Cage* is implanted via an anterior or posterior approach and is combined with supplemental fixation.

For either intended use, the *ATLAS Intervertebral Body Cage* must be used with supplemental internal fixation.

Prescription Use: X AND/OR Over-The-Counter Use:
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

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