K060916

5.0 510(k) Summary

1. Sponsor

JUN - 8 2006

Spinal Edge, LLC
780 W Army Trail Road # 218
Carol Stream, Illinois 60188-9297

Primary Contact: Yashdip Pannu M.D.
Telephone: 630.903.4364

Date Prepared: April 5, 2006 (Revised May 23, 2006)

2. Device Name:

Proprietary Name:	ATLAS Spinal Cage
Common/Usual Name:	Spinal Vertebral Body Replacement Device
Classification Name:	Spinal Vertebral Body Replacement Device (21 CFR 888.3060), Class II

3. Predicate Devices

K990148 – Stackable Cage System – DePuy AcroMed, Inc.
K040284 – Sustain Radiolucent Spacer – Globus Medical, Inc.

4. Device Description

The Spinal Edge ATLAS Spinal Cage is a vertebral body replacement 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 spacer has an axial hole to allow optional grafting material to be packed inside of the spacer. Protrusions on the superior and inferior surfaces of each device will grip the cortical endplates of the adjacent vertebrae to resist expulsion

5. Intended Use

The Spinal Edge ATLAS Spinal Cage is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damage or unstable vertebral body due to tumor or trauma. The Spinal Edge ATLAS Spinal Cage is intended to be used with supplemental spinal fixation system(s) 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 of the spacer may if indicated

be packed with bone grafting material. The Spinal Edge ATLAS Spinal Cage is designed to provide anterior spinal column support for a prolonged period of time even in the absence of fusion.

6. Technological Characteristics and Substantial Equivalent

The ATLAS Spinal Cage and its predicate devices have the same indications for use and are made of the same materials. Testing to demonstrate with FDA's Guidance for Spinal System 510(k) May 3, 2004 was completed for the Spinal Edge ATLAS Spinal Cage.

7. Performance Testing

The testing was conducted to validate the ATLAS Spinal Cage in accordance with MTI Protocol PR465-0001 and ASTM F2077-03, "Test Methods for Intervertebral Body Fusion Devices" demonstration compliance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2006

Spinal Edge, LLC
c/o Ms. Christina Vacca
25125 Detroit Road
Westlake, Ohio 44145

Re: K060916
Trade/Device Name: ATLAS Spinal Cage System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: April 4, 2006
Received: April 4, 2006

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.

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 (301) 443-6597 or at its 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

4.0 Indications for Use Statement

510(k) Number (if Known): K060916

Indications For Use:

The Spinal Edge ATLAS Spinal Cage is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damage or unstable vertebral body due to tumor or trauma. The Spinal Edge ATLAS Spinal Cage is intended to be used with supplemental spinal fixation system 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 of the spacer may if indicated be packed with bone grafting material. The Spinal Edge ATLAS Spinal Cage is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period of time.

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

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

510(k) Number K060916

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