K091110

JUL 24 2009

10.0 510(k) Summary

1. Sponsor

Spinal Edge LLC
2275 Research Blvd. Suite 527
Rockville, MD 20805

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

Date Prepared: March 20, 2009

2. TITAN Pedicle Screw System:

Proprietary Name:	***TITAN Pedicle Screw System***
Common/Usual Name:	Pedicle Screw Spinal System
Classification Name:	Pedicle Screw Spinal System (21 CFR 888.3070), Class II Product Codes MNH, MNI

3. Predicate Devices

K030383 – DePuy 5.5 Moss Miami Ti
K024348, K023438, K021335 - DePuy AcroMed MONARCH Spine System

4. Device Description

The *Spinal Edge* ***TITAN Pedicle Screw System*** consists of longitudinal rods, polyaxial screws, and transverse connectors. The *Spinal Edge* ***TITAN Pedicle Screw System*** components are available in titanium alloy conforming to ASTM F-136 specifications.

5. Intended Use

The *Spinal Edge* ***TITAN Pedicle Screw Systems*** is intended for posterior, noncervical pedicle fixation for the following indications: spondylolisthesis; trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The device is to be used in skeletally mature patients, and for stabilization and immobilization of the spine as an adjunct to fusion with bone graft. The levels of fixation are T8 – S1.

6. Technological Characteristics and Substantial Equivalent

The *Spinal Edge* **TITAN** ***Pedicle Screw System*** and its predicate device(s) have the same indications for use, operating principles and are made of the same materials.

Representative samples of the device underwent testing to demonstrate comparable function and performance characteristics to the predicate device.

7. Performance Testing

The testing method for the ***TITAN Pedicle Screw System*** was completed in accordance with ASTM F1717 "Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Model". Part number SE-112-CA-5.75 55mm length screw was used for testing. The longest pedicle screw was tested to provide greatest potential for bending stress.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2009

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

Re: K091110
Trade/Device Name: Titan Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: June 30, 2009
Received: July 7, 2009

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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buchner
for

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): K091110

Indications for Use:

The *Spinal Edge **TITAN Pedicle Screw Systems*** is intended for posterior, noncervical pedicle fixation for the following indications: spondylolisthesis; trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The device is to be used in skeletally mature patients, and for stabilization and immobilization of the spine as an adjunct to fusion with bone graft. The levels of fixation are T8 – S1.

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)

Page 1 of 1

(EXT for M/M)

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

510(k) Number K091110