JAN 27 2014

510(k) Summary

Date:	27 September 2013
Sponsor:	K7 LLC 54 Moonrise Way Henderson, NV 89074 Phone: 817.219.4441 Facsimile: 817.326.5524
Contact Person:	Michael D. Smith, Manager
Trade Names:	Aversion Pedicle Screw System
Device Classification	Class II
Classification Name:	Pedicle screw spinal system
Regulation:	888.3070
Device Product Code:	MNI/MNH
Device Description:	The Aversion Pedicle Screw System consists of straight and curved rods, polyaxial pedicle screws and crosslink connectors. These are available in a variety of sizes to accommodate differing patient anatomy.
Intended Use:	The Aversion Pedicle Screw System is intended for posterior, noncervical (T1-S1) pedicle fixation to provide immobilization and stabilization in skeletally mature patients as an adjunct to fusion for the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudarthrosis and failed previous fusion
Materials:	The Aversion Pedicle Screw System is manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136.
Predicate Devices:	CD HORIZON® (K031655/K041460) Moss® Miami (K992168/K022623) Synergy™ VLS (K950099/K974749) Viper™2 (K090648)
Performance Data:	Static compression bending and torsion, and dynamic compression bending tests were performed according to ASTM F1717 on the worst case Aversion screw. In addition, pullout testing according to ASTM F543 was performed on the worst case Aversion screw. The mechanical test results demonstrate that the Aversion Pedicle Screw System performance is substantially equivalent to the predicate devices.

Technological Characteristics:

The Aversion Pedicle Screw System components possess the same technological characteristics as the predicate devices. These include:

- basic design (rod-based pedicle screw fixation system),
- material (titanium alloy),
- anatomic location (non-cervical spine) and
- sizes (widths, lengths and heights are within the range(s) offered by the predicate systems).

Technological characteristics which are different have been supported with descriptive information and/or performance data.

Conclusion:

In comparison to the predicate devices, the Aversion Pedicle Screw System has

- the same intended use (as described above),
- the same technological characteristics or different without raising safety and effectiveness issues (as described above)

Therefore the Aversion Pedicle Screw System can be found substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 27, 2014

K7, LLC
% Karen E. Warden, Ph.D.
BackRoads Consulting, Incorporated
P.O. Box 566
Chesterland, Ohio 44026-0566

Re: K133103
Trade/Device Name: Aversion Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: January 20, 2014
Received: January 22, 2014

Dear Dr. Warden:

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 contact 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. 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,

Lori A. Wiggins

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

Enclosure

Indications for Use Statement

510(k) Number: K133103

Device Name: **Aversion Pedicle Screw System**

Indications for Use:

The Aversion Pedicle Screw System is intended for posterior, noncervical (T1-S1) pedicle fixation to provide immobilization and stabilization in skeletally mature patients as an adjunct to fusion for the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudarthrosis and failed previous fusion.

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133103