K101278

8. 510(k) Summary

DEC 2 0 2010

Date:	4 May 2010
Sponsor:	Nexxt Spine LLC 10142 Brooks School Road Fishers, IN 46037 Phone (317) 436.7801 Fax (317) 245.2518
Contact Person:	Andy Elsbury, President
Proposed Trade Name:	Inertia™ Pedicle Screw System
Device Classification	Class II
Classification Name:	Pedicle screw spinal system
Regulation:	888.3070
Device Product Code:	MNI; MNH
Device Description:	The Inertia™ Pedicle Screw System consists of rods, polyaxial screws and set screws. Rods are available in either straight or pre-contoured (curved) forms and in a variety of lengths. Polyaxial screws are available in a variety of diameter-length combinations. Set screws are used to fasten the rod and polyaxial screw.
Intended Use:	The Inertia™ Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T1 to S2): 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; spinal tumor; and failed previous fusion (pseudarthrosis).
Materials:	The Inertia™ Pedicle Screw System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.
Predicate Devices:	CD HORIZON® (K031655, K041460) Moss Miami (K992168, K022623) Synergy VLS (K950099, K974749) Optima™ Spinal System (K024096, K031585, K051971)

Technological Characteristics:	The Inertia™ Pedicle Screw System possesses the same technological characteristics as the predicates. These include: • basic design: rod-based pedicle screw system having polyaxial screws, • material: titanium alloy, • sizing: rod and screw sizes are within the range of those in the predate systems, and • intended use: as described above Therefore the fundamental scientific technology of the Inertia™ Pedicle Screw System is the same as previously cleared devices.
Performance Data:	Static compression bending and torsion and dynamic compression bending of the worst case Inertia™ Pedicle Screw System construct was performed according to ASTM F1717. The mechanical results demonstrated that the Inertia™ Pedicle Screw System performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Nexxt Spine LLC
% Backroads Consulting Inc.
Karen E. Warden, Ph.D.
8202 Sherman Road
Chesterland, Ohio 44026-2141

DEC 2 0 2010

Re: K101278
Trade/Device Name: Inertia™ Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWP
Dated: November 26, 2010
Received: November 30, 2010

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 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,

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

Enclosure

7. Indications for Use Statement

510(k) Number: K101278

Device Name: **Inertia™ Pedicle Screw System**

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Indications for Use:

The Inertia™ Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T1 to S2): 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; spinal tumor; and failed previous fusion (pseudarthrosis).

Prescription Use __X__ AND/OR Over-the-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS 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

510(k) Number K101278