

## 8. 510(k) Summary

**Sponsor:** Nexxt Spine LLC  
10142 Brooks School Road  
Fisher, IN 46037  
Phone (317) 436.7801  
Fax (317) 245.2518

JUN 30 2009

**Contact Person:** Andy Elsbury, President

**Proposed Trade Name:** Inertia™ Pedicle Screw System

**Device Classification:** Class II

**Classification Name:** Orthosis, spinal pedicle fixation; orthosis, spondylolisthesis spinal fixation

**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: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; 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.

**Substantial Equivalence:** Documentation was provided which demonstrated the Inertia Pedicle Screw System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in basic design, intended use, indications, anatomic sites and mechanical performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Nexxt Spine, LLC  
% Mr. Andy Elsbury  
President  
10142 Brooks School Road  
Fisher, Indiana 46037

JUN 30 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Re: K090984  
Trade/Device Name: Inertia™ Pedicle Screw System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: II  
Product Code: MNI, MNH  
Dated: April 3, 2009  
Received: April 7, 2009

Dear Mr. Elsbury:

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.

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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/cdrh/mdr/> 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/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Barbara Melkerson" with a small mark below the name.

Mark N. Melkerson

Director

Division of Surgical, Orthopedic,  
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

