

510(k) Summary

Device Trade Name: Inertia™ MIS Pedicle Screw System

Manufacturer: Nexxt Spine, LLC
14425 Bergen Blvd Suite B
Noblesville, IN 46060

Contact: Eric Lintula
Director of Engineering and Regulatory Affairs
Phone: 317.840.3816

Date Prepared: July 31, 2013

Classifications: 21 CFR §888.3070, Pedicle screw spinal system.

Class: II

Product Codes: MNH, MNI, KWP

OCT 10 2013

Indications For Use:

The Inertia™ MIS 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).

Device Description:

The Inertia™ MIS 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.

The purpose of this 510(k) is to add cannulated pedicle screws to the Inertia™ MIS Pedicle Screw System.

Predicate Device:

The subject Inertia™ MIS Pedicle Screw System is substantially equivalent to predicate Inertia™ Pedicle Screw System (K101278, K090984) with respect to indications, design, function, and materials.

Substantial Equivalence:

Mechanical testing (static, dynamic compression bending, static torsion) was performed according to ASTM F1717 on the worst case subject Inertia™ MIS Pedicle Screw System and predicate Inertia™ Pedicle Screw System. The results demonstrate that the acceptance criteria defined in the Design Control Activities Summary were met.



October 10, 2013

Nexxt Spine, LLC
% Mr. Justin Eggleton
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street Northwest, 12th Floor
Washington, District of Columbia 20005

Re: K132412
Trade/Device Name: Inertia™ MIS 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: September 11, 2013
Received: September 13, 2013

Dear Mr. Eggleton:

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

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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 CDRI'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,

Erin D. Keith

for

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

Enclosure

Indications for Use

510(k) Number (if known)
K132412

Device Name
Inertia(TM) MIS Pedicle Screw System

Indications for Use (Describe)

The Inertia™ MIS 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).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Ronald P. Jean -S