DEC - 7 2011

Royal Oak Medical Devices
Athena Pedicle Screw System

510(K) Summary

SUBMITTED BY	Royal Oak Medical Devices 39533 Woodward Avenue, Suite 175 Bloomfield Hills, MI 48304 USA
ESTABLISHMENT REGISTRATION NUMBER	Pending
OWNER/OPERATOR NUMBER	Pending
CONTACT PERSON	Matthew Kroll Vice President of Technical Services Royal Oak Medical Devices Phone: 248-628-2830 Fax: 248-969-8263
SUBMISSION PREPARED BY	Anne Wilson QA Consulting,Inc. 9433 Bee Cave Road Bldg.1, Suite 140 Austin, TX 78733 Phone: 512-328-9404 Fax: 512-532-9434
DATE PREPARED	22 September 2011
CLASSIFICATION NAME	Pedicle Screw Spinal System
DEVICE CLASS	Class III (product code NKB) Class II (product codes MNI, MNH)
REGULATION NUMBER	NKB 888.3070 MNI 888.3070 MNH 888.3070
COMMON NAME	Spinal Fixation System
PROPRIETARY NAME	Athena Pedicle Screw System
IDENTIFICATION OF	The Athena Pedicle Screw System is

PREDICATE DEVICE(S)

substantially equivalent to the Interpore Cross Synergy Polyaxial System (K950099/K974749), Rogozinski System (K930298/K983904) and Depuy Spine Moss Miami System (K992168/K022623)

DEVICE DESCRIPTION

The Athena Pedicle Screw System is comprised of polyaxial pedicle screws in various diameters and lengths, spinal rods in various lengths, cross-connectors and set screws. The Athena Pedicle Screw System can be used for single or multiple level fixations. All implant components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136.

INDICATIONS:

The Athena Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients. The system is intended for posterior, pedicle fixation as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The purpose of this submission is to obtain clearance to market the Athena Pedicle Screw System. The Athena Pedicle Screw System implants are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136. The subject device has similar technological characteristics as the predicate devices identified above. Specifically, the following characteristics support this conclusion:

- Same intended use.
- Substantially equivalent results of non-clinical testing relative to static and dynamic testing (per ASTM F1717).

DISCUSSION OF NON-CLINICAL TESTING

The following non-clinical tests were conducted, the results of which demonstrate that the Athena Pedicle Screw System is substantially equivalent to the predicate(s):

- Static and dynamic axial compression bending testing, conducted in accordance with ASTM F1717
- Static torsion testing, conducted in accordance with ASTM F1717

CONCLUSIONS

The subject and predicate device(s) share the same intended use, primary implant design and equivalent material of manufacture. The non-clinical mechanical test results demonstrate that any minor differences do not impact device performance as compared to the predicates and demonstrate that the Athena Pedicle Screw System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Royal Oak Medical Devices
% Mr. Matthew Kroll
Vice President of Technical Services
39533 Woodward Avenue, Suite 175
Bloomfield Hills, Michigan 48304

DEC - 7 2011

Re: K110046
Trade/Device Name: Athena Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: December 1, 2011
Received: December 2, 2011

Dear Mr. Kroll:

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

INDICATIONS FOR USE

510(k) Number: K110046

Device Name: **Athena Pedicle Screw System**

Indications for Use:

The Athena Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients. The system is intended for posterior, pedicle fixation as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K110046