MAR - 3 2011

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter Information

Submitter's Name:	Apollo Spine
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Contact Person:	Christine Santagate , STD Medical
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Date Prepared:	September 10, 2010
Device Trade Name:	Zenith Pedicle Screw System
Common/Usual Name:	Pedicle Screw Spinal System
Class:	II
Product Code(s):	MNH, MNI
Regulation Number(s):	888.3070 Noncervical, Pedicle System

Predicate Device (s):

- Stryker Xia Pedicle Screw Spinal System, K013823
- Amedica Valeo Pedicle Screw System, K07343

Substantial Equivalence:

The Zenith Pedicle Screw System was shown to be substantially equivalent to previously cleared devices and had the same indications for use, design, function, and materials used.

Device Description:

The Apollo Spine Zenith Pedicle Screw System consists of a variety of rods and screws, which can be rigidly locked into a variety of configurations, with each construct being tailor made for the individual case. Multi axial implant screws are supplied in 5.5mm, 6.5mm, 7.5mm and 8.5mm diameter sizes. All sizes are able to receive 5.5 mm connecting rods only. All implant components are fabricated from medical grade titanium alloy (TI-6AI-4V ELI) conforming to ASTM F136 or equivalent.

The Apollo Spine Zenith Pedicle Screw System is a temporary implant system, intended to be removed after solid fusion has occurred. Implant components should not be used with components from any other system or manufacturer. As with all orthopedic implants, components should not be reused.

Indications For Use:

The Zenith Spinal 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: degenerative spondylolisthesis with objective evidence of neurologic impairment, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), spinal tumor, and failed previous fusion (pseudarthrosis).

In addition, this device is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3-S1) with removal of implants after the attainment of a solid fusion.

Mechanical Test Data:

The following testing was performed on this device:

- Static Torsion per ASTM F 1717-04
- Static Compression Testing per ASTM F 1717-04
- Dynamic Compression Testing per ASTM F 1717-04
    - Includes 2 runout samples to 5 million cycles

Conclusion:

ASTM Standard F 1717 was adhered to and all applicable requirements were met. Testing results demonstrate that the Zenith Pedicle Screw System is substantially equivalent to publically available data for the predicate devices and therefore demonstrate its suitability for its intended use.

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

Apollo Spine, Inc.
% STD Medical, Inc.
Ms. Christine Santagate
75 Mill Street
Stoughton, Massachusetts 02072

MAR - 3 2011

Re: K102636
Trade/Device Name: Zenith Pedicle System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: February 07, 2011
Received: February 08, 2011

Dear Ms. Santagate:

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,

for

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 Statement

510(k) Number (if known):

Device Name: Zenith Pedicle System

Indications for Use:

The Zenith Pedicle 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: degenerative spondylolisthesis with objective evidence of neurologic impairment, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), spinal tumor, and failed previous fusion (pseudarthrosis).

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 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 K102636