510(k) Summary

MAR 1 3 2014

Submission Date:	March 13, 2014
Submitter Information:	Alphatec Spine, Inc. 5818 El Camino Real Carlsbad, CA 92008 Ph: (760) 431-9286 Fax: (760) 431-0289
Contact:	Renée L. Murphy Sr. Regulatory Affairs Specialist Ph: (760) 494-6739
Trade/Model Name:	**Arsenal Spinal Fixation System™**
Common Name:	Pedicle Screw System
Classification Regulation:	21 CFR 888.3070, Pedicle screw spinal system, Class III
Product Code(s):	OSH, NKB, MNI, MNH

Device Description

The Arsenal Spinal Fixation System is a Class III non-cervical, posterior approach pedicle screw system. The Arsenal Spinal Fixation System allows surgeons to perform posterior thoracolumbar spine fusion utilizing both implants for fixation and ergonomic instruments to meet the surgeon's needs.

This traditional 510(k) submission adds a new pedicle screw system to Alphatec Spine's current offering and provides the following:

- Polyaxial, Reduction, Sacral, and Cortical non-cannulated, titanium, self-tapping, pedicle screws
- Cancellous, Sacral, and Cortical dual lead threadforms
- Titanium set screws
- Straight and pre-contoured rods in titanium and cobalt chromium
- Titanium connectors which include Variable Bridges, Offset Connectors, Revision Connectors, Axial Connectors and Domino Connectors
- Instrumentation necessary to perform posterior fixation system procedures
- Connects with other Alphatec Spine systems to provide fixation for the entire spine

Indications for Use

The Arsenal Spinal Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (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; pseudarthrosis; and/or failed previous fusion.

When used for posterior non-cervical screw fixation in pediatric patients, the Arsenal Spinal Fixation System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally the Arsenal Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach.

The Arsenal Spinal Fixation System is intended to be used with autograft and/or allograft.

Substantial Equivalence Claimed

The Arsenal Spinal Fixation System is substantially equivalent to the Alphatec Spine, Inc., Zodiac® Spinal Fixation System (K100685) for implants, instruments, indications for use, labeling, materials, design, technology and performance. In addition, the Arsenal Spinal Fixation System is substantially equivalent to the Medtronic Sofamor Danek USA, Inc., CD Horizon® Spinal System (K130646) for implants, instruments, and indications for use.

Technical Characteristics

The intended use and technological design features of the Arsenal Spinal Fixation System are similar to the predicate Zodiac Spinal Fixation System. Both are pedicle screw systems intended for posterior non-cervical screw fixation as an adjunct to fusion. In addition, both systems have the same technical characteristics in terms of design and materials.

Non-Clinical Performance Testing

Performance testing was conducted in accordance with Static Compression per ASTM F1717, Dynamic Compression per ASTM F1717, Static Torsion per ASTM F1717, Fatigue Run-out per ASTM F1798, Static Interconnection per ASTM F1798, Static Axial Grip per ASTM F1798, Torsional Gripping Capacity per ASTM F1798 and Neutral/Maximum Angulation Pull-off Strength testing.

Test results demonstrate that this new pedicle screw system is substantially equivalent to the predicate Zodiac Spinal Fixation System.

Conclusion

The Arsenal Spinal Fixation System is substantially equivalent to the predicates in terms of components, indications for use, design, materials, labeling, technology and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 13, 2014

Alphatec Spine, Incorporated
Ms. Renée L. Murphy
Senior Regulatory Affairs Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K133221
Trade/Device Name: Arsenal Spinal Fixation System™
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH
Dated: February 12, 2014
Received: February 14, 2014

Dear Ms. Murphy:

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 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" (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,

Lori A. Wiggins

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133221

Device Name
Arsenal Spinal Fixation System

Indications for Use *(Describe)*
The Arsenal Spinal Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (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; pseudarthrosis; and/or failed previous fusion.

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The Arsenal Spinal Fixation System is intended to be used with with autograft and/or allograft.

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)*

Colin O'Neill

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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