Alphatec Spine

510(k) SUMMARY
May 2010

Submitter: Alphatec Spine, Inc.
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JUL 21 2010

Official Contact: Karla Schaffner, Regulatory Affairs Submissions Specialist

Trade/Model Name: Alphatec Spine Anterior Lumbar Plating System

Common Name: Spinal Intervertebral Body Fixation Orthosis

Classification Regulation: KWQ - 888.3060 - Appliance, Fixation, Spinal Intervertebral Body

Substantial Equivalence:
The Alphatec Spine Anterior Lumbar Plating System is substantially equivalent in intended use and function to the following predicate devices:

Company	System	Clearance
Spinal USA	Anterior Lumbar Plate System	K091044
Blackstone Medical	Unity Anterior Lumbar Plate Fixation System	K043548
Blackstone Medical	Unity LX Anterolateral Lumbar Plate Fixation System	K061229

Device Description:
The Alphatec Spine Anterior Lumbar Plating System is a spinal fixation system that consists of a variety of non-sterile, single-use plates and screws. All implants are manufactured from titanium alloy conforming to ASTM F136. The system also contains Class I manual instruments. The plates attach to the anterior or anterolateral aspect of the vertebral body of the lumbar/lumbosacral spine (levels L1-S1) providing temporary internal fixation and stabilization during bone graft healing and/or fusion mass development.

Intended Use
The Alphatec Spine Anterior Lumbar Plating System is intended for use as an anteriorly placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels. The device is intended as a temporary fixation device until fusion is achieved.
The Alphatec Spine Anterior Lumbar Plating System is intended for anterior lumbar spine (L1-S1) fixation for the following indications:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies)
2. Pseudoarthrosis
3. Spondylolysis
4. Spondylolisthesis
5. Trauma (i.e., fracture or dislocation)
6. Spinal stenosis
7. Unsuccessful previous fusion surgery
8. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
9. Tumor

The Alphatec Spine Anterior Lumbar Plating System is intended to be used with autograft and/'or allograft as an adjunct to fusion.

Technological Characteristics Comparison:
The Alphatec Spine Anterior Lumbar Plating System is equivalent to the referenced device in that it is intended to be used to provide temporary internal lumbar/lumbosacral spine fixation and stabilization during bone graft healing and/or fusion mass development. It is similar in terms of general design, intended use, and technological characteristics to the predicate device.

Material composition is identical to numerous other Alphatec Spine products that have been cleared via the 510(k) process.

Nonclinical Performance Data:
Mechanical static compression and torsion and dynamic testing was performed which provides reasonable assurance of safety and effectiveness for its intended use. Performance testing was performed per the recognized consensus standards and per the guidance document, *Spinal System 510(k)s - Guidance for Industry and FDA Staff.* This testing clearly demonstrated that the performance characteristics satisfy the requirements of anterior / anterolateral lumbar fixation. As a results of this testing have demonstrated that the Alphatec Spine Anterior Lumbar Plating System is substantially equivalent to the Spinal USA 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

JUL 21 2010

Alphatec Spine, Inc.
% Ms. Karla Schaffner
Regulatory Affairs Submission Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K101255
Trade/Device Name: Alphatec Spine Anterior Lumbar Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 03, 2010
Received: May 04, 2010

Dear Ms. Schaffner:

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

Section 4 Indications for Use Statement

510(k) Number (if known): TBD K101255

Device Name: Alphatec Spine Anterior Lumbar Plating System

Indications for Use:
The Alphatec Spine Anterior Lumbar Plating System is intended for use as an anteriorly placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels. The device is intended as a temporary fixation device until fusion is achieved.

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Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(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 K101255