

MAR 26 2004

ZODIAC Polyaxial Pedicle Screw System  
510(k) SUMMARY  
November 2003

K033090  
1 of 2

**Company:** Alphatec Manufacturing, Inc.  
6110 Corte Del Cedro  
Carlsbad, CA 92009 USA  
Telephone: (760) 431-9286  
Fax: (760) 431-9132

**Contact Person:** Ellen Yarnall, Director of Regulatory Affairs

**Trade/Proprietary Name:** ZODIAC Polyaxial Pedicle Screw System

**Common Name:** Pedicle Screw Spinal System

**Classification Name:** Spinal Interlaminar Fixation Orthosis (888.3050)  
Spondylolisthesis Spinal Fixation Device (888.3070)  
Pedicle Screw Spinal System (888.3070)

**Product Description:**

The ZODIAC Polyaxial Pedicle Screw System is comprised of various types and sizes of implantable components that are assembled to create a rigid spinal construct. System components are manufactured from titanium alloy, Ti-6Al-4V ELI (ASTM F 136). System rods are available in titanium alloy or commercially pure titanium, CP Grade 4 (ASTM G67). The ZODIAC Polyaxial Pedicle Screw System is designed to facilitate optimal screw and rod placement.

**Indications for Use:**

It is intended that this device, in any system configuration be removed after development of solid fusion mass. Hook component indications are limited to T7-L5. Sacral screw indications are limited to the sacrum only.

- 1) The ZODIAC Polyaxial Pedicle Screw System, when used as a hook and sacral screw fixation system (nonpedicle screw) is intended for:
  - a. Patients having fractures of the thoracic and lumbar spine.
  - b. Patients having deformity (i.e., idiopathic scoliosis, neuromuscular scoliosis, or kyphoscoliosis with associated paralysis or spasticity).
  - c. Patients having spondylolisthesis (i.e., isthmic spondylolisthesis, degenerative spondylolisthesis, and acute pars fracture allowing spondylolisthesis).

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- 2) The ZODIAC Polyaxial Pedicle Screw System, when used as a pedicle screw system in the thoraco-lumbo-sacral region of the spine is intended for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).
- 3) In addition, the ZODIAC Polyaxial Pedicle Screw System, when used as a pedicle screw fixation system is intended for:
  - a. Patients receiving only autogenous bone graft.
  - b. Patients having the device fixed or attached to the lumbar and sacral spine and having severe spondylolisthesis grade 3 or 4 at the fifth lumbar-first sacral (L5-S1) vertebral joint.
- 4) The ZODIAC Polyaxial Pedicle Screw System, when used as a laminar hook and bone screw system is intended for:
  - a. Patients having fractures of thoracic and lumbar spine.
  - b. Patients having thoracolumbar deformity (i.e., idiopathic scoliosis, neuromuscular scoliosis, or kyphoscoliosis with associated paralysis or spasticity).
  - c. Patients having spondylolisthesis (i.e., isthmic spondylolisthesis, degenerative spondylolistheses and acute pars fracture allowing spondylolisthesis).

**Substantial Equivalence:**

The ZODIAC Polyaxial Pedicle Screw System is substantially equivalent to the following predicate devices:

<u>Trade/Proprietary Name</u>	<u>Manufacturer</u>	<u>Clearance</u>
Optima Spinal System	U&I America	K031585
Global Spinal Fixation System	U&I America	K001668
Moss-Miami Spinal System	Depuy Inc.	K982320
Universal Spine System	Synthes	K022949

**Performance Data:**

Mechanical and dynamic testing of the ZODIAC Polyaxial Pedicle Screw System was performed. The test results demonstrate that the mechanical performance of the ZODIAC Polyaxial Pedicle Screw System is at least comparable to, if not better than, those of the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 26 2004

Ms. Ellen Yarnell  
Director, Regulatory Affairs  
Alphatec Manufacturing Incorporated  
6110 Corte Del Cedro  
Carlsbad, California 92009

Re: K033090  
Trade Name: ZODIAC Pedicle Screw System  
Regulation Number: 21 CFR 888.3050 and 888.3070 (b) (1)  
Regulation Name: Spinal Interlaminar Fixation Orthosis and Pedicle Screw Spinal System  
Regulatory Class: Class II  
Product Code: KWP, MNI, MNH  
Dated: January 8, 2004  
Received: January 9, 2004

Dear Ms. Yarnell:

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.

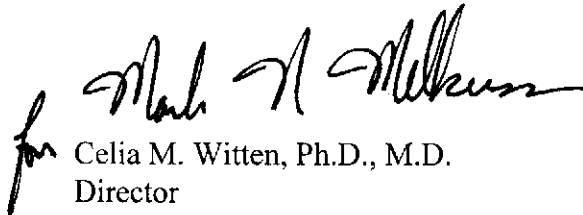
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

01022  
K033090

MAR 26 2004

INDICATIONS FOR USE

510(k) Number (if known): K033090

Device Name: ZODIAC Polyaxial Pedicle Screw System

**Indications for Use:**

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*for Mark A. Miller*  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

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- c. Patients having spondylolisthesis (i.e., isthmic spondylolisthesis, degenerative spondylolistheses and acute pars fracture allowing spondylolisthesis).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_

*for Mark A. Melkers*  
 (Division Sign-Off)  
 Division of General, Restorative,  
 and Neurological Devices

510(k) Number K033090