OCT 27 2004

K042673 - 510(k) SUMMARY
ZODIAC™ Polyaxial Spinal Fixation System
September 2004

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 Spinal Fixation System

Common Name: Pedicle Screw Spinal System

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

Product Description:

The ZODIAC™ Polyaxial Spinal Fixation 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). This submission seeks clearance for a line extension.

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 Spinal Fixation 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., idioscoliosis, 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).

2) The ZODIAC™ Polyaxial Spinal Fixation 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 Spinal Fixation 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 Spinal Fixation 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., idioscoliosis, 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:

Documentation was provided that demonstrates that the ZODIAC™ Polyaxial Spinal Fixation System is substantially equivalent to other pedicle screw systems currently on the market.

Performance Data:

Mechanical and dynamic testing was performed. Test results demonstrated that the mechanical performance of the ZODIAC™ Polyaxial Spinal Fixation System is at least comparable to, if not better than, those of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2004

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

Re: K042673
Trade/Device Name: ZODIAC™ Polyaxial Spinal Fixation System
Regulation Numbers: 21 CFR 888.3050 and 21 CFR 888.3070 (b) (1)
Regulation Names: Spinal interlaminal fixation orthosis and Pedicle screw spinal system
Regulatory Class: II
Product Codes: KWP, MNI, MNH
Dated: September 29, 2004
Received: September 29, 2004

Dear Ms. Yarnall:

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 (240) 276-0120. 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,

for Mark N. Melkerson

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

INDICATIONS FOR USE

510(k) Number (if known): K042673

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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 General, Restorative, and Neurological Devices

510(k) Number K042673