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K022376 p1/2

Alpha Mirage® Top Tightening Spinal System
510(k) SUMMARY
February 2002

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

II. **Contact Person**: Ellen Hicks, Director of Regulatory Affairs

III. **Trade/Proprietary Name**: Alpha Mirage® Top Tightening Spinal System

IV. Product Description:

The purpose of this 510(k) is to expand the indications for use and to add components to the system.

The Alpha Mirage® Top Tightening Spinal System is a spinal fixation system comprised of various types and sizes of components that are implanted via a posterior surgical approach and assembled to create a spinal construct. Like most other posterior spinal fixation systems, the Alpha Mirage® Top Tightening Spinal System is comprised of 1) bone screws and hooks for attachment to the spine, 2) longitudinal rods that are attached to the bone screws and hooks directly/indirectly by means of lateral connectors, and that transmit loads across the pathologic segments of the spine, and 3) optional transverse connecting elements that link the two longitudinal rods for added construct stability.

V. Intended Use:

The Alpha Mirage® Top Tightening Spinal System is intended for use as a posterior spinal fixation device to aid in the surgical correction of various spinal deformities and pathologies in the thoraco-lumbo-sacral portion of the spine. It is intended to provide stabilization during the development of fusion utilizing a bone graft. Specific indications for the Alpha Mirage® Top Tightening Spinal System are dependent in part on the configuration of the assembled device and method of attachment to the spine.

VI. Substantial Equivalence:

The expanded indications for the Alpha Mirage® Top Tightening Spinal System are substantially equivalent to the following predicate device:

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Alpha Mirage® Top Tightening Spinal System
510(k) SUMMARY
February 2002

Trade/Proprietary Name	Manufacturer	Clearance
TSRH	Sofamor-Danek	K982990

The new pedicle screw classification indications described in the classification Final Rule, July 17, 1998 were referenced. Applicable specifications, testing and validation was included in other 510(k) applications or are included in this application.

VI. Performance Data:

Mechanical and dynamic testing of the Alpha Mirage® Top Tightening Spinal System constructs was performed as described in 510(k) applications K951846 and K930515. The test results demonstrated that the mechanical performance and biocompatibility characteristics are at least comparable to, if not better than, those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2002

Ms. Ellen Hicks
Director of Regulatory Affairs
Alphatec Manufacturing, Inc.
6110 Corte Del Cedro
Carlsbad, California 92009

Re: K020356
Trade/Device Name: Alpha Mirage® Top Tightening Spinal System
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050, 21CFR 888.3060
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: MNH, MNI, KWP, KWQ
Dated: June 10, 2002
Received: June 11, 2002

Dear Ms. Hicks:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K020356

Device Name: Alpha Mirage® Top Tightening Spinal System

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 Alpha Mirage® Top Tightening Spinal 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 Alpha Mirage® Top Tightening Spinal 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 tumore and failed previous fusion (pseudoarthrosis).

3) In addition, the Alpha Mirage® Top Tightening Spinal 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 Alpha Mirage® Top Tightening Spinal System, when used as a laminar hook and bone screw system is intended for:

   a. Patients having fractures of thoracic and lumbar spine.

for Mark N Milleman
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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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).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The Counter Use _____

(Per 21 CFR 801.109)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020356