K041469

JUL 3 0 2004

PREMARKET NOTIFICATION 510(K) SUMMARY

Company:

X-Spine Systems
7026 Corporate Way, #212
Centerville, OH 45459-4288
Telephone: 800/903-0640
Fax: 866/481-0740

Company Contact: David Kirschman, MD

Date: May 28, 2004

Proposed Proprietary Trade Name: Anterior Compact Plate (ACP) System

Classification Name: Orthopedics, 888.3060, Class II

FDA Product Code Classification: KWQ

Device Description: The X-Spine Anterior Compact Plate (ACP) System includes titanium alloy anterior cervical plates and bone screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine, levels C2 to C7. The implant components are provided clean and non-sterile.

Intended Use:

The X-Spine ACP System is intended for anterior screw fixation to the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

Predicate Device: Synthes CSLP System

Performance Data: Performance data were submitted to characterize the X-Spine ACP System.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2004

X-Spine Systems, Inc.
C/o Ms. Janet M. Webb
MEDVantage, Inc.
121 W. Chestnut Street, #3506
Chicago, Illinois 60610

Re: K041469
Trade/Device Name: X-Spine Systems Anterior Compact Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: May 28, 2004
Received: June 2, 2004

Dear Ms. Webb:

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,

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

Indication for Use Statement

510(k) Number (if known): K041469

Device Name: X-Spine Systems Anterior Compact Plate System

Indications for Use:

The X-Spine ACP System is intended for anterior screw fixation to the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e., fractures or dislocations),
- Tumors,
- Deformity (defined as kyphosis, lordosis, or scoliosis)
- Pseudoarthrosis, and/or
- Failed previous fusions.

Prescription Use _____X_____ or Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

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

510(k) Number K041469

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