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K051697

510(k) SUMMARY

Medical Device Advisory Development Group's Selective-Axis Posterior Noncervical Plating System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Medical Device Advisory Development Group
560 Old Ranch Road
Seal Beach, CA 90740

Phone: 562-598-1753
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Contact Person: Robert S. Howland

Date Prepared: June 22, 2005

Name of Device and Name/Address of Sponsor

Selective-Axis Posterior Noncervical Plating System

Medical Device Advisory Development Group
560 Old Ranch Road
Seal Beach, CA 90740

Common or Usual Name

Posterior Pedicle Screw System

Classification Name

Orthosis, Spinal Pedicle Fixation; Orthosis, Spondylolisthesis Spinal Fixation (21 C.F.R. § 888.3070); Product Code: MNI, MNH

Predicate Devices

EBI's SpineLink-II Spinal Fixation System
Scient'x Aladyn Rigid Spine Plate

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Intended Use / Indications for Use

The Selective-Axis Posterior Noncervical Plating System is intended for use as a posterior, noncervical (thoracic, lumbar and sacral), pedicle screw fixation system for the following indications: degenerative disc disease ("DDD") (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (*i.e.,* fracture or dislocation), spinal stenosis, tumor, pseudoarthrosis, and failed fusion.

Technological Characteristics and Substantial Equivalence

The Selective-Axis Posterior Noncervical Plating System ("Selective-Axis Plating System") is comprised of the following components: Selective-Axis anchor screw assemblies, connecting beam assemblies, and jam nuts. All of the components of the Selective-Axis Plating System are manufactured from Ti6Al4V-ELI titanium alloy per ASTM F136.

The Selective-Axis Plating System is substantially equivalent* to the other currently marketed spinal systems which are referenced above. The Selective-Axis Plating System and its predicate devices all employ multi-angular pedicle screws, longitudinal plates or bars that connect the pedicle screws, cross-linking connectors that connect the longitudinal plates or bars, and locking nuts with similar technological features to stabilize the spine as

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* Any statement made in conjunction with this submission regarding an FDA determination of substantial equivalence to any other product is intended only to relate to whether the product can be marketed lawfully under FDA's section 510(k) premarket notification process. The term "substantial equivalence" as used herein is not related to "substantial equivalence" as the term is used in the patent context. [See Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

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an adjunct to fusion. Thus, the Selective-Axis Plating System raises no new issues of safety or effectiveness.

Performance Data

Mechanical testing of the Selective-Axis Plating System was performed in accordance with FDA's Guidance for Industry and FDA Staff - Spinal System 510(k)s, dated May 3, 2004.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Medical Device Advisory Development Group
C/o C. Stephen Lawrence
Hogan & Hartson L.L.P.
Century Centre
2603 Main Street, Suite 1170
Irvine, CA 92614

Re: K051697
Trade/Device Name: Selective-Axis Posterior Noncervical Plating System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: June 22, 2005
Received: June 23, 2005

Dear Mr. Lawrence:

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/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K051697

Device Name: **Selective-Axis Posterior Noncervical Plating System**

Indications for Use:

The Selective-Axis Posterior Noncervical Plating System is intended for use as a posterior, noncervical (thoracic, lumbar and sacral) pedicle screw fixation system for the following indications: degenerative disc disease ("DDD") (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (*i.e.*, fracture or dislocation), spinal stenosis, tumor, pseudoarthrosis, and failed fusion.

Prescription Use √ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 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 General, Restorative, and Neurological Devices

510(k) Number K051697