K040747

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510(k) Summary

Date
March 17, 2004

JUN 17 2004

Submitter
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Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name
Posterior pedicle screw system

Classification name
Spondylolisthesis spinal fixation device system
Pedicle screw spinal system

Equivalent Device
The Aladyn Rigid Spine Plate is a modification to the ISOLOCK (K990721) and ISOBAR (K990118) Pedicle Screw Systems.

Device Description
The Aladyn Rigid Spine Plate consists of plates, pedicle screws and a polyaxial nut. It is a modification to the plates and nuts of the ISOLOCK Pedicle Screw System (K990721) and uses the same hemispherical screws of the ISOBAR system (K990118). Pedicle screws are inserted into the pedicles of the vertebrae. An Aladyn plate is placed over the screws. The rigid plates are available in six multi-hole lengths. The construct is then securely fixed with nuts. The implantation steps of the Aladyn are the same as the ISOLOCK Plate system. The only difference is that there are no washers used with the Aladyn plate.

The hemispherical screws come in two diameters (6.2mm and 7.0mm) and in lengths ranging from 38mm to 50mm. There is also a polyaxial nut available.

Intended Use
The Aladyn Rigid Spine Plate is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

As a pedicle screw system Aladyn Rigid Spine Plate is indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Summary Nonclinical Tests
Testing was performed per ASTM F1717. Results were comparable with other devices on the ISOLOCK and ISOBAR Pedicle Screw Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2004

Scient'x
c/o Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K040747
Trade/Device Name: Aladyn Rigid Spine Plate
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI
Dated: May 17, 2004
Received: May 18, 2004

Dear Mr. 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 Milhern

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

510(k) number (if known): K040747

Device Name: Aladyn Rigid Spine Plate

Indications for Use:

Aladyn Rigid Spine Plate
Indications for Use

The Aladyn Rigid Spine Plate is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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(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 ____

(Optional format 1-2-96) ____

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

510(k) Number

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

 510(k) Number K040747