K101374

1.4 510(k) SUMMARY

MAR 16 2011

510(K) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a)

Submission Information:

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R&D Dept.

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Data Prepared: May 11, 2010

Device Identification

Trade Name: Aaxter A3 Posterior Spinal System
Common Name: Pedicle Screw Spinal System

Classification Name:
a) Appiliance, Fixation, Spinal Interlaminal (KWP per 21 CFR) § 888.3050
b) Spinal Pedicle Fixation Orthosis (MNI) Per 21 CFR § 888.3070
c) Spondylolisthesis Spinal Fixation Orthosis (MNH) per 21 CFR § 888.3070

K101374

Substantially Equivalent Predicate Legally Marketed Devices:

The Subject Aaxter A3 Posterior Spinal System is substantially equivalent in function materials, design, operational principles, composition, labeling, and intended use to:

OPTIMA™, Spinal System MNI, MNH-(K031585)
U&I America, Spinal Hook System™, KWP-(K031595)

Device Description:

The Aaxter A3 Posterior Spinal System is a posterior spinal system which is a top loading multiple components, posterior pedicle and hook fixation system intended to provide segmental stabilization of spinal segments in skeletally mature patients as an adjunct to fusion.

The Aaxter A3 Posterior Spinal System consists of variety of rods, hooks, screws, and cross links used to build a spinal construct for stabilization and promotion of spinal fusion in the thoracic-lumbar and sacral regions.

The Aaxter A3 Posterior Spinal System implant system components are supplied non-sterile for single use and are made from medical titanium alloy (Ti-6Al-4V) that conforms to ASTM F136. Specialized instruments made from surgical grade stainless steel are used for all the operations of the Aaxter A3 Posterior Spinal System.

Indications for Use:

The Aaxter A3 Posterior Spinal System is intended for posterior pedicle and non-pedicle fixation in the non-cervical spine as an adjunct to fusion in skeletally mature patients for the following indication: spondylolisthesis (Grade 3 and 4), of the L5-S1 vertebra in skeletally-mature patients receiving fusion by autogenous bone graft having implants attainment to the lumbar and sacral spine with removal of implants after the attainment of a solid fusion.

In addition, the Aaxter A3 Posterior Spinal System is 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 of the vertebral body
- Dislocation

- Scoliosis
- Kyphosis
- Spinal tumor

Statement of Technological Comparison:

The subject spinal implant system is substantially equivalent to the above listed predicate device in terms of material, design, indications for use and operational principles.

Performance data:

Static compression bending, static torsion and dynamic compression bending testing per ASTM F1717 and pullout testing per ASTM F1798 were performed on the Aaxter A3 Posterior Spinal System. Test results were substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 16 2011

Aaxter Co., Ltd.
% Mr. Eric Kung
4905 Washtenaw Avenue
Ann Arbor, Michigan 48108

Re: K101374
Trade/Device Name: Aaxter A3 Posterior Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: March 11, 2011
Received: March 11, 2011

Dear Mr. Kung:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101374
Device Name: Aaxter A3 Posterior Spinal System
Indications for Use:

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- Dislocation
- Scoliosis
- Kyphosis
- Spinal tumor

Prescription Use X **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(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 Surgical, Orthopedic,
and Restorative Devices

4--25

510(k) Number K101374