PREMARKET NOTIFICATION 510(K) SUMMARY

JUL - 9 2010

Company:
Allure Spine L.L.C.
Owner, Regulatory Affairs and Quality Assurance
9214 Sandpiper Drive
Charlotte, NC 28277
Telephone: (440) 339-8709
Fax: (704) 220-0515

Company Contact: Julia Eller

Date: March 29, 2010

Trade/Device Name: Spondy™ Spinal Fixation System
Regulatory Number: Orthosis 21 CFR 888.3070
Regulation Name Pedicle Screw Spinal System
Regulatory Classification: Class II
FDA Product Code ; MNI, MNH
Classification Advisory Committee ; Orthopedic
Review Advisory Committee; Orthopedic

Device Description:

The Spondy Spinal Fixation System is a top-loading spinal fixation system consisting of polyaxial screws, set screws, rods, and cross connectors assembled to create a rigid spinal construct. It is intended to provide stabilization during the development of fusion utilizing a bone graft as well as aid in the surgical correction of various spinal deformities and pathologies in the thoracolumbo-sacral iliac portion of the spine. The titanium alloy, single-use components are provided clean and non-sterile. Various sizes of the implants (screws and rods) are available to accommodate individual patient anatomy.

Indications for Use/Intended Use:

The Spondy Spinal Fixation System is a posterior, noncervical pedicle fixation 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 including degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, when used as a pedicle screw fixation system, the Spondy Spinal Fixation System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, who are receiving fusion by autogenous bone graft

only having the device attached to the lumbar and sacral spine (levels are L3-sacrum/ilium), who are having the device removed after the attainment of a solid fusion.

Predicate Device:

Predicate device information is included. The Spondy Spinal Fixation System is substantially equivalent to the predicate devices: *Perfix™ Spinal System* (K091725), The *OPTIMA™* Spinal System (K024096), *the HydraLok™* (K051216), and the Synergy VLS (K950099, K041449).

Performance Data:

Performance data was submitted to characterize the Spondy Spinal Fixation System. Mechanical and dynamic testing was performed which provides reasonable assurance of safety and effectiveness for its intended use. Testing consisted of Static Compression Bending Testing per ASTM F1717, Dynamic Compression Bending Testing per ASTM F1717, Static Tension Testing per ASTM F1717, and Static Torsion Testing per ASTM F1717.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUL - 9 2010

Allure Spine, L.L.C.
% Ms. Julia Eller
Regulatory Affairs, Quality Assurance
9214 Sandpiper Drive
Charlotte, North Carolina 28277

Re: K100956
Trade/Device Name: SPONDY™ SPINAL FIXATION SYSTEM
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI
Dated: June 24, 2010
Received: June 29, 2010

Dear Ms. Eller:

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,

Barbara Boehm for

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/Intended Use Statement

510(k) Number (if known): K100956

Device Name: SPONDY™ SPINAL FIXATION SYSTEM

Indications for Use:

The Spondy™ Spinal Fixation System is a posterior, non-cervical pedicle fixation 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 including degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, when used as a pedicle screw fixation system, the Spondy Spinal Fixation System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral, L5-S1 vertebra, who are receiving fusion by autogenous bone graft only, who are having the device attached to the lumbar and sacral spine (levels may be from L3 to the sacrum/ilium), who are having the device removed after the attainment of a solid fusion.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100956