K103748

510(k) Summary

[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

MAR - 2 2011

Contact:

Mr. Hartmut Loch
Vice President, Regulatory Affairs & Quality Assurance
Phygen, LLC.
2301 Dupont Drive, Suite 510
Irvine CA 92612

Date Prepared: February 23, 2011

Trade name: *LAGUNA® Pedicle Screw System*

Common name: Spinal Fixation System

Classification name:

Appliance, Fixation, Spinal Interlaminal - § 888.3050 (KWP) – class II
Orthosis, Spinal Pedicle Fixation - § 888.3070 (MNI) – class II
Orthosis, Spondylolisthesis Spinal Fixation § 888.3070 (MNH) – class II
Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease - § 888.3070 (NKB) – class III

All Orthopedic Device Panel

Product Code (s): KWP, MNI, MNH & NKB

Device Description and Characteristics: The *LAGUNA® Pedicle Screw System* is intended to help provide correction, immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral space. The LAGUNA® Pedicle Screw System consists of a variety of rods and screws, which can be rigidly locked into a variety of configurations, with each construct being tailor made for the individual case. Polyaxial screws are supplied in winged and non-winged configurations, in a variety of different length, ranging from 30 mm to 100 mm and 5 mm, 6 mm, 7 mm and 8mm diameter sizes. All sizes are able to receive 5.5mm connecting rods only.

The LAGUNA® Pedicle Screw System implant components are fabricated from medical grade titanium alloy per ASTM F136.

Equivalence: The modified *LAGUNA® Pedicle Screw System* is substantially equivalent to the original *LAGUNA® Pedicle Screw System (K083826, K091995, K050060, K072678)*, which are manufactured and marketed by Phygen,LLC.

Indications: The LAGUNA® Pedicle Screw System is intended to be used as an adjunct to fusion in skeletally mature patients using autograft or allograft in posterior, non-cervical fixation for the following conditions: degenerative disc disease (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; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumors; pseudarthrosis; and/or failed previous fusion.

Performance data: Biomechanical tests per ASTM F1717-10 (Static Compression Bending, Static Torsion, and Dynamic Compression Bending) have been performed. The test results were equivalent to other similar implants and are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Phygen, LLC
% Mr. Hartmut Loch
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Re: K103748
Trade/Device Name: LAGUNA® Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: December 22, 2010
Received: December 23, 2010

Dear Mr. Loch:

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): **K103748**

Device Name(s): LAGUNA® Pedicle Screw System

Indications for Use:

The LAGUNA® Pedicle Screw System is intended to be used as an adjunct to fusion in skeletally mature patients using autograft or allograft in posterior, non-cervical fixation for the following conditions: degenerative disc disease (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; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumors; pseudarthrosis; and/or failed previous fusion.

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

510(k) Number K103748