



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Kisco International
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

September 17, 2015

Re: K152098
Trade/Device Name: ODALYS™ Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: July 27, 2015
Received: July 28, 2015

Dear Dr. Jansen:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K152098

Device Name

ODALYST™ Pedicle Screw System

Indications for Use (Describe)

The ODALYST™ Pedicle Screw System 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 ODALYST™ Pedicle Screw System 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared: July 27, 2015

Submitter Contact: Hiroko Ito
Kisco International
2 Place Berthe Morisot
Saint-Priest, France 69800
Tel : +33 (0)4 78 90 85 59
Fax : +33 (0)4 78 90 85 18

Regulatory Contact: Rich Jansen, Pharm. D.
Silver Pine Consulting, LLC
richj@s-pineconsulting.com

Trade name: ODALYS™ Pedicle Screw System
Common Name: Pedicle screw system
Classification Name: Pedicle Screw Spinal System
21 CFR Sec. 888.3070
MNI, MNH
Class II

Predicate or legally marketed device which is substantially equivalent:

Odalys Pedicle Screw System (K111370)

Description of the device:

The ODALYS™ Pedicle Screw System has been developed with the objective of providing the surgeon with an adaptable fixation system in order to carry out dorsal stabilization of the spine simply, quickly and effectively.

The system consists of a variety of color coded top loading pedicle screws. The pedicle screws are available in various lengths and diameters. The screw is connected to the rod via a rod connector. Two sizes of connectors are available, short and long. The long is used in cases of spondylolisthesis where the short connector would not be able to engage the rod. The rods are available in multiple lengths.

Materials:

The components are manufactured from titanium alloy (Ti 6Al 4V ELI) per ASTM F136.

Function:

The ODALYS™ Pedicle Screw System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments until fusion takes place.

Substantial equivalence claimed to predicate devices:

The ODALYS™ Pedicle Screw System is substantially equivalent to the ODALYS™ Pedicle Screw System in terms of intended use, design, materials used, and performances.

Indications for Use:

The ODALYS™ Pedicle Screw System 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 ODALYS™ Pedicle Screw System 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 of Nonclinical Tests:

The following tests were conducted:

- Static and dynamic compression per ASTM F1717
- Static torsion per ASTM F1717

The results of this testing indicate that the ODALYS™ Pedicle Screw System is equivalent to predicate devices.

Clinical Test Summary:

No clinical studies were performed

Technological Characteristics:

Kisco International, SA has compared the Odalys Pedicle Fixation System to the predicate device in regards to indications for use, materials, function, sizes and mechanical test results. These comparisons demonstrate substantial equivalence to the predicate devices.

Conclusions:

The ODALYS™ Pedicle Screw System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.