510(k) Summary

JAN 13 2014

Date Prepared: September 27, 2013

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Trade Names: Santis Pedicle Screw System
Product Class: Class III
Classification: 21 CFR §888.3070 Pedicle Screw Spinal System,
Common Name: Pedicle Screw System
Product Codes: MNI, MNH, NKB
Panel Code: 87

Indications for Use:
The Santis Pedicle System is intended for immobilization and stabilization of the spine. The Santis Pedicle System is indicated for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (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); tumor; pseudoarthrosis; and failed previous fusion.

Device Descriptions:
The Santis Pedicle Screws System Spinal Fixation is comprised of: straight and pre-curved rods, pedicle screw assemblies with both cannulated and non-cannulated screws, compression retaining assemblies, cross connectors and a set screw. Various forms and sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology of individual patients. The Santis system can be implanted either by an open procedure or percutaneous MIS approach, or a combination of both during the same procedure.
Components are made of Ti6Al4V ELI, a titanium based alloy, which complies with ASTM F136, or cobalt chrome per ASTM F1537.

Predicate Device(s):

The Santis Pedicle Screw is substantially equivalent to the AnyPlus Spinal Fixation System from GS Medical (K091717).

Predicate Comparison:

Feature	Santis Pedicle Screw System	AnyPlus Spinal Fixation System
Indications for Use	See above	AnyPlus Spinal Fixation System are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system (T1-L5), or as a anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. System components are to be used for immobilization and stabilization of the spine as an adjunct to fusion. These devices are indicated for all of the following regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuemann's Disease), tumor, stenosis, pseudoarthrosis and failed previous fusion.
Screw types	Cannulated and non-cannulated screws in both regular and reduction screws	Cannulated and non-cannulated screws non-cannulated reduction screws
Screw sizes	Diameters: 5.5, 6.5 and 7.5mm Lengths: 30-60mm	Diameters: 5.5, 6.5 and 7.5mm Lengths: 30-55mm
Straight Titanium rods	Diameter 5.5mm Lengths 40-500mm	Diameter 5.5mm Lengths 40-500mm
Straight CoCr Rods	Diameter 5.5mm Lengths 250 & 500mm	NA
Pre-curved titanium rods	Diameter 5.5mm Lengths 40-200mm	Diameter 5.5mm Lengths 40-200mm
Polyaxial head and polyaxial reduction head	5.5, 6.5, 7.5mm	5.5, 6.5, 7.5mm
Swivel cross connector	30, 40 and 50mm	35. 38, 42, 50mm
Straight cross connector	30, 40 and 50mm	NA

Performance Standards:
The pre-clinical testing performed includes static and dynamic compression bending, static torsion and static tension bending per ASTM F1717-10, axial grip strength per ASTM F1798-97, and three point bend test per ASTM F543-07.

Conclusion:
Lanterna concludes that the Santis Pedicle Screw System is substantially equivalent to the predicate pedicle screw system in regards to indications for use, materials, function, sizes and mechanical test results and raises no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 13, 2014

Lanterna Medical Technologies
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
13540 Guild Avenue
Apple Valley, Minnesota 55124

Re: K133063
Trade/Device Name: Santis Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: October 24, 2013
Received: October 24, 2013

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 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. 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 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,

Ronald P. Jean -S for

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

Enclosure

Indications for Use Statement

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Prescription Use ___V____ (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 Center for Devices and Radiological Health (CDRH)

Zane W. Wyatt -S

(Division Sign-off)
Division of Orthopedic Devices
510(k) Number: K133063