K111940

MAY 15 2012

510(k) Summary
for the S 100 Pedicle Screw System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the S 100 Pedicle Screw System

Date Prepared: July 1, 2011

1. **Submitter:**
Renovis Surgical Technologies
1901 W. Lugonia Ave, Ste 340
Redlands, CA 92374

2. **Contact Person:**
J.D. Webb
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Round Rock, TX 78681
512-388-0199
512-6923699
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2. **Trade name:** S 100 Pedicle Screw System
Common Name: pedicle screw system
Classification Name: orthosis, spondylolisthesis spinal fixation/ MNH/ 888.3070
orthosis, spinal pedicle fixation/ MNI/ 888.3070
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
Renovis S 100 Pedicle Screw System -
ZODIAC™ Polyaxial Spinal Fixation - K042673 (Alphatec Spine Co)
Xia3 - K071371 & K083393 (Stryker Spine)

4. **Description of the device:**
As a posterior pedicle screw system designed for temporary stabilization of the posterior spine during the development of spinal fusion, the Renovis S 100 Pedicle Screw System is comprised of polyaxial pedicle screws, rods, and crosslinks. The S 100 System can be used for single or multiple level fixations

The screws are a top loading tulip design and are available in multiple diameters and lengths. Reduction screws are available for cases of spondylolisthesis where the short arms of the tulip of the standard screw are not long enough to engage the rod. The rods are available in straight and pre-lordosed (curved) configurations. The system also has variable and fixed crosslinks.

The purpose for this Premarket Notification is for the addition of iliac screws and connectors.

Materials:
The components are manufactured from titanium alloy ELI (ASTM F136), CP titanium Grade 4(ASTM F67) and CoCrMo (ASTM F1537.

Function:
The S 100 Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments until fusion takes place.

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5. **Substantial equivalence claimed to predicate devices:**

   The S 100 Pedicle Screw System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

6. **Intended Use:**

   The Renovis S 100 Pedicle Screw 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 thoracic, lumbar, and sacral spine: failed previous fusion (pseudoarthrosis), spinal stenosis, degenerative spondylolisthesis with objective evidence of neurological impairment, spinal deformations such as scoliosis or kyphosis and loss of stability due to tumors or trauma (fracture and dislocation).

   When used as a pedicle screw system, the Renovis S 100 Pedicle Screw System is intended for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae 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.

7. **Summary of Nonclincal Tests:**

   The following tests were conducted:

   - Testing per ASTM F1717 (static and dynamic compression, and static torsion)

   The results of this testing was compared to predicate devices, with the results being equal to, or higher, than the predicates.

8. **Clinical Test Summary:**

   No clinical studies were performed

9. **Conclusions Nonclinical and Clinical:**

   The Renovis S 100 Pedicle Screw System is substantially equivalent to the predicate devices in terms of indications for use, design, material, function and method of assembly.

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

Renovis Surgical Technologies, LLC
% The OrthoMedix Group
Mr. J.D. Webb
1001 Oakwood Blvd.
Round Rock, Texas 78681

MAY 15 2012

Re: K111940
Trade/Device Name: S 100 Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: February 06, 2012
Received: April 19, 2012

Dear Mr. Webb:

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.

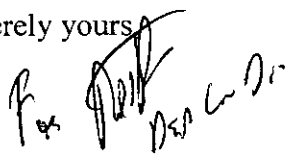
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

K111940

510(k) Number (if known): _____

Device Name: Renovis S 100 Pedicle Screw System

Indications for Use:

The Renovis S 100 Pedicle Screw 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 thoracic, lumbar, and sacral spine: failed previous fusion (pseudoarthrosis), spinal stenosis, degenerative spondylolisthesis with objective evidence of neurological impairment, spinal deformations such as scoliosis or kyphosis and loss of stability due to tumors or trauma (fracture and dislocation).

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 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 K111940

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