510(k) Summary

Submitter: Sanacor LLC

JUN 13 2007

Contact Person:
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Date Prepared: March 27, 2007

Trade Name: LowTop Pedicle Screw System

Classification, Name and Number:
Class II
Pedicle Screw System
21 CFR 888.3070

Product Code: MNI and MNH

Predicate Device(s): The subject device is substantially equivalent to the following devices:

ConKlusion Pedicle Screw System (K031455)
Marketed and distributed by Signus Medical LLC

Optima Pedicle Screw System (K020279)
Marketed and distributed by Zimmer Spine

OvalTwist Pedicle Screw System (K061577)
Marketed and distributed by Signus Medical LLC

Device Description: The LowTop Pedicle Screw System is a spinal system that consists of screws, rods, connectors and associated instruments. Fixation is provided by bone (pedicular) screws inserted into the vertebral body of the spine using a posterior approach.

Intended Use: The LowTop 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 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 (Pseudoarthrosis).

	In addition, this device is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 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 S1) with removal of the implants after the attainment of a solid fusion.
Functional and Safety Testing:	Mechanical testing of the subject device consisted of static compression bending, static torsion and dynamic compression bending. All testing was conducted in accordance with ASTM F1717. The device performed as designed and met, or exceeded, all product specifications.
Conclusion:	Sanacor LLC considers the LowTop Pedicle Screw System to be equivalent to the predicate devices listed above. This conclusion is based on the devices' similarities in functional design

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sanacor LLC
c/o Mr. Michael Ensign
Director of Engineering
765 East 340 South, Suite 204
American Fork, Utah 84003

JUN 13 2007

Re: K070933
Trade/Device Name: LowTop Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: March 30, 2007
Received: April 6, 2007

Dear Mr. Ensign:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~NA~~ K070933

Device Name: LowTop Pedicle Screw System

Indications for Use: The LowTop System is intended for posterior, non-cervical pedicle fixation for the following indications:

- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

In addition, this device is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 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 S1) with removal of the implants 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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070933