K090477

JUL 27 2009

510(k) Summary

Submitter:	Sanacor LLC
Contact Person:	Mr. Michael Ensign, Regulatory Affairs Manager Sanacor LLC P.O. Box 1196 Pleasant Grove, UT 84062 Telephone: (801) 358-9986 Fax: (801) 785-9415
Date Prepared:	February 19, 2009
Trade Name:	Alpine 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: *Mesa Pedicle Screw System* Marketed and distributed by K2M, Inc. *OvalTwist Pedicle Screw System* (K061577) Marketed and distributed by Signus Medical LLC
Device Description:	The Alpine Pedicle Screw System is a spinal system that consists of screws, rods, 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 Alpine 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

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	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, dynamic compression bending, and axial grip. All testing was conducted in accordance with ASTM F1717 and F1798. The device performed as designed and met, or exceeded, all product specifications.
Conclusion:	Sanacor LLC considers the Alpine Pedicle Screw System to be equivalent to the predicate devices listed above. This conclusion is based on the devices' similarities in function, design, materials, and indications for use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 7 2009

Sanacor LLC
% Mr. Michael Ensign
Director of Engineering
PO Box 1196
Pleasant Grove, UT, 84062

Re: K090477
Trade/Device Name: Alpine Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI
Dated: July 20, 2009
Received: July 22, 2009

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 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.

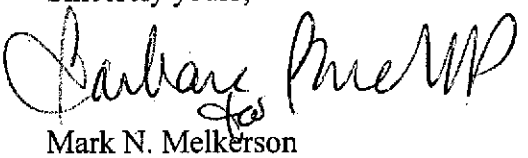
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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____

Device Name: Alpine Pedicle Screw System

Indications for Use:

The Alpine 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.

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)

(EXT for AXM)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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