510(k) Summary

JUL - 3 2008

Submitter: Sanacor LLC

Contact Person: Mr. Michael D. Ensign
Sanacor LLC
765 E 340 S Suite 204
American Fork, UT 84003
Telephone: (801) 756-6249
Fax: (801) 756-8286

Date Prepared: March 13, 2008

Trade Name: Active Anterior Cervical Plate System

Classification: Class II

Classification Name: Appliance, fixation, spinal intervertebral body

Number: 21 CFR 888.3060

Product Code: KWQ

Predicate Device(s): The subject device is substantially equivalent to the following systems which are currently marketed and distributed in the US:

PreView Anterior Cervical Plate (K062371), Sanacor

CSLP (K030866), Synthes

DOC VCSS (K982443), DePuy Spine

C-Jaws Cervical Compression Mini Frame (K062181)
Medicrea Technologies

OSStaple Staple System (K061385), BioMedical Enterprises, Inc.

Pioneer Anterior Cervical Plate System (K043066)
Pioneer Surgical Technology

Ant-Cer Dynamic Anterior Cervical Plate System (K024326)
Spinal Concepts, Inc.

Synthes Vectra-T System (K051665), Synthes Spine

C3 Anterior Cervical Plate System (K012881), Spine Vision

Device Description: The Active™ Anterior Cervical Plate System is a fixation system designed to allow for settling of the bone graft during fusion. Plates are provided in various lengths to accommodate fusions from 1 to 4 levels. Fixed and variable angle locking unicortical screws are provided in lengths of 12, 14, 16, and 18mm and diameters of 4mm and 4.5mm.

Intended Use: The Active™ Anterior Cervical Plate System is intended for the treatment of the cervical spine in skeletally mature patients receiving fusion by autogenous and/or allogenic bone graft. The implants are attached to the anterior cervical spine (C2-T1) with removal of the implants after the attainment of a solid fusion mass. The Active™ Anterior Cervical Plate System is intended for use under the following indications:

- Degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Basis of Substantial Equivalence: The Active Anterior Cervical Plate System is substantially equivalent to the above listed predicate devices.

The substantially equivalent technological characteristics found in the Active Anterior Cervical Plate System include the following:

- Augment stability of grafted segment
  PreView (K062371), CSLP (K030866)
- Segmented plate to allow screw translation via carriages
  DOC (K982443), Vectra (K051665), Ant-Cer (K024326)
- Combined use of two titanium alloys: Nitinol and Ti-6Al-4V
  Pioneer (K043066)
- Compression applied to bone graft
  OSStaple (K061385), C-JAWS (K062181), C3 (K012881)

All of these technologies are substantially equivalent to those found among the predicate devices.

Mechanical performance attributes per ASTM F1717 were found to be substantially equivalent to those of predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sanacor, LLC
% Mr. Michael Ensign
Regulatory Manager
765 East 340 South, Suite 204
American Fork, Utah 84003-3348

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Re: K073500
Trade/Device Name: Activc™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis.
Regulatory Class: II
Product Code: KWQ
Dated: May 2, 2008
Received: May 5, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

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): K073500

Device Name: Active™ Anterior Cervical Plate System

Indications for Use: The Active™ Anterior Cervical Plate System is intended for the treatment of the cervical spine in skeletally mature patients receiving fusion by autogenous and/or allogenic bone graft. The implants are attached to the anterior cervical spine (C2-T1) with removal of the implants after the attainment of a solid fusion mass. The Active™ Anterior Cervical Plate System is intended for use under the following indications:

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- Tumor
- Pseudoarthrosis
- Failed previous 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 K073500