K080815

7. 510(k) Summary

APR 23 2008

Sponsor:	SIGNUS Medizintechnik GmbH Carl-Zeiss-Strasse 2 D-63755 Alzenau, GERMANY Tel. + 49 (0) 6023 9166-136 Fax + 49 (0) 6023 9166-161 Url: http://www.signus-med.de
Contact Person:	Elisabeth Wroblewski, Regulatory Affairs, QMR
Proposed Trade Name:	TOSCA II Anterior Cervical Plate System
Regulation	888.3060 – Spinal Intervertebral Body Fixation Orthosis
Device Class	Class II
Device Product Code:	KWQ
Device Description:	The TOSCA II Anterior Cervical Plate System comprises plate and screw components in a variety of sizes and lengths. Variable angle screws and a Center graft screw are offered.
Intended Use:	The TOSCA II Anterior Cervical Plate System is intended for anterior cervical fixation for the following indications: degenerative disc disease (as defined by 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, pseudarthrosis and failed previous fusion. WARNING: The TOSCA II Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
Materials:	The TOSCA II Anterior Cervical Plate System components are manufactured from titanium alloy (Ti-6Al-4V per ASTM F136).
Substantial Equivalence:	Documentation was provided which demonstrated the TOSCA II Anterior Cervical Plate System to be substantially equivalent to the previously cleared TOSCA Anterior Cervical Plate System. The substantial equivalence is based upon equivalence in basic design, intended use, indications, anatomic sites and performance.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SIGNUS Medizintechnik GmbH
% Karen E. Warden, Ph.D.
Representative/Consultant
8202 Sherman Road
Chesterland, OH 44026

APR 23 2008

Re: K080815
Trade/Device Name: TOSCA II Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: March 20, 2008
Received: March 24, 2008

Dear Dr. Warden:

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) 638-2041or (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

6. Indications for Use Statement

510(k) Number: K080815

Device Name: **TOSCA II Anterior Cervical Plate System**

Indications for Use:

The TOSCA II Anterior Cervical Plate System is intended for anterior cervical fixation for the following indications: degenerative disc disease (as defined by 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, pseudarthrosis and failed previous fusion.

WARNING: The TOSCA II Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Prescription Use X OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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