K012305

AUG 2 2 2001

510(k) Summary

Submitter's Information

Date:	July 20, 2001
Name/Address:	Sulzer Spine-Tech 7375 Bush Lake Road Minneapolis, Minnesota 55439
Telephone Number: Fax Number:	(952) 830-6205 (952) 832-5620
Contact:	Janell A. Colley Senior Regulatory Affairs Specialist

Device Information

Trade Name:	Trinica™ Anterior Cervical Plate System
Common Name: Orthosis	Spinal Intervertebral Body Fixation
Classification:	Class II, KWQ
Predicate Device:	Michelson Anterior Cervical Plate K974435 concurrence date February 19, 1998

Device Description:
The Trinica Anterior Cervical Plate System is a fixation device consisting of cervical plates, locking caps, fixed bone screws and variable angle bone screws made from titanium alloy in conformance with ASTM F136. The locking cap is preassembled onto the plate and is designed with tabs that prevent bone screws from backing out. The plates and locking caps are treated with titanium anodization per AMS (Aerospace Material Specification) 2488 Type II. Bone screws are subjected to a color anodizing process to differentiate the screw type and diameter

Plates are offered in one-level, two-level, three-level, and four-level fusion configurations (24 mm through 92 mm). Bone screws are available in lengths from 10mm through 18mm in 1mm increments. The screws have either a 4.2 inch 4.6 inch diameter. Fixed angle and variable angle screws are available.

Intended Use:
The Trinica Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine at levels C2-T1. The System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Comparison of Required Technological Characteristics
The Trinica Anterior Cervical Plate System is substantially equivalent to the predicate Michelson Anterior Cervical Plate System (K974435). The table below provides a comparison of equivalency characteristics.

Characteristics	Equivalency
Intended Use	Identical
Anatomical Sites	Identical
Target Population	Identical
Sterilization	Identical
Packaging	Identical
Operating Principle	Identical
Materials	Identical
Labeling	Substantially Equivalent
Physical Characteristics (Design)	Substantially Equivalent
Performance Testing	Substantially Equivalent
Safety Characteristics	Substantially Equivalent

Summary of Non-Clinical Tests
Based on risk analysis, appropriate testing was conducted to evaluate the impact of the changes to ensure that the modified device meets established criteria and that identified potential risks were mitigated. Results of the testing demonstrated that the modified device meets established criteria.

Conclusions Drawn From Testing
Testing of the Trinica Anterior Cervical Plate System demonstrates that the device is substantially equivalent to the predicate Michelson Anterior Cervical Plate System (K974435) and that the design modifications do not affect device safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2001

Ms. Janell A. Colley
Senior Regulatory Affairs Specialist
Sulzer Spine-Tech
7375 Bush Lake Road
Minneapolis, MN 55439-2027

Re: 510(K) Number K012305
Trade/Device Name: Trinica™ Anterior Cervical Plate System
Regulation Number: 21 CFR § 888.3060
Regulatory Class: II
Product Code: KWQ
Dated: July 20, 2001
Received: July 23, 2001

Dear Ms. Colley:

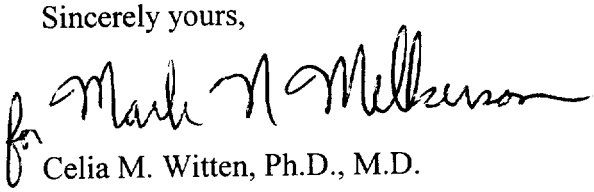
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

Indications for Use Statement

510(K) Number: **K012305**

Device Name:
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Indications for Use:

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PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milkerson

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

Prescription Use _____ 510(k) Number K012305 **OR Over-the-Counter-Use**
(Per 21 CFR 801.109)