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SEP 24 2002

5. 510(k) Summary

Submitter's Information

Date:	July 24, 2002
Name/Address:	Centerpulse Spine-Tech 7375 Bush Lake Road Minneapolis, Minnesota 55439
Telephone Number:	(952) 830-6284
Fax Number:	(952) 832-5620
Contact:	Tim Miller Director of Clinical and Regulatory Affairs

Device Information

Trade Name:	Trinica Select™ Anterior Cervical Plate System
Common Name:	Spinal Intervertebral Body Fixation Orthosis
Classification:	Class II, KWQ
Predicate Devices:	Trinica™ Anterior Cervical Plating System K012305, concurrence date August 22, 2001 Michelson Anterior Cervical Plate K974435, concurrence date February 19, 1998 Synthes Anterior Cervical Spine Locking Plate K945700, concurrence date July 20, 1995 Synthes Spine Small Stature Anterior Cervical Vertebrae Plate System™ K971883, concurrence date October 16, 1997 Medtronic Sofamor-Danek Zephir™ Anterior Cervical Plate System K994239, concurrence date June 19, 2000

Device Description:
The Trinica Select 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 (22 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/Trinica Select 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 Select™ Anterior Cervical Plate System is substantially equivalent to the predicate Synthes anterior cervical spine system (K945700, concurrence date July 20, 1995). 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 Select Anterior Cervical Plate System demonstrates that the device is substantially equivalent to the devices 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

SEP 2 4 2002

Timothy Miller
Director of Clinical and Regulatory Affairs
Centerpulse Spine-Tech, Inc.
7375 Bush Lake Road
Minneapolis, Minnesota 55439-2027

Re: K022344
Trade/Device Name: Trinica Select Anterior Cervical Plate System
Regulatory Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: August 28, 2002
Received: August 29, 2002

Dear Mr. Miller:

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 and additionally 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

for Mark N Melkerson

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

Enclosure

2. Indications for Use Statement

510(K) Number: K022344 **(Pending)**

Device Name:
Trinica/Trinica Select™ Anterior Cervical Plate System

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)

Prescription Use

for Marlene N. Millhouse

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

510(k) Number K022344

Over-the-Counter-Use
(Per 21 CFR 801.109)