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MAR - 5 2004

Centerpulse Spine-Tech, Inc.
(d/b/a Zimmer Spine)

510(k) Summary
(21 CFR Part 807.92)

A. Submitter Information

Submitter's Name:	Tim Crabtree
Address:	7375 Bush Lake Road Minneapolis, MN 55439-2027
Telephone Number:	(952) 857-5631
Fax Number:	(952) 832-5931
Contact Person:	Tim Crabtree
Date Submission Prepared:	May 13, 2003

B. Device Information

Trade Name:	DYNESYS® Spinal System
Common or Usual Name:	rod, hook, and screw spinal instrumentation
Classification Name:	(per 21 CFR Part 888.3070)
Device Classification:	Class II (per 21 CFR Part 888.3070) Panel –Orthopedic
Predicate Device:	Silhouette™ Spinal Fixation System (K980288)

Subject Device Description:

The DYNESYS® Spinal System consists of four pedicle screws, two cords and two spacers in a symmetric, bilateral arrangement. The pedicle screws are placed lateral to the facet joints with two screws in the cephalad position and two screws in the caudad position. The superior-inferior distance between the pedicle screws is maintained with the spacers. The cord passes through the eye of the pedicle screw heads and through the centers of the spacers.

Intended Use:

When used as a pedicle screw fixation system in skeletally mature patients, the DYNESYS Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and

chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, kyphosis, and failed previous fusion (pseudoarthrosis).

In addition, when used as a pedicle screw fixation system, the DYNESYS Spinal System is indicated for use in patients:

a) Who are receiving fusions with autogenous graft only;
b) Who are having the device fixed or attached to the lumbar or sacral spine; and
c) Who are having the device removed after the development of a solid fusion mass.

C. Substantial Equivalence

The technological characteristics of the DYNESYS® Spinal System are similar to the following commercially available devices:

- Silhouette™ Spinal Fixation System (K980288), manufactured by Centerpulse Spine-Tech, Inc. and cleared by the FDA on July 29, 1998.

Establishment of equivalence is based on similarities of intended use, design, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2004

Mr. Tim Crabtree
Senior Regulatory Affairs Specialist
Centerpulse Spine-Tech, Inc.
7375 Bush Lake Road
Minneapolis, Minnesota 55439-2027

Re: K031511
Trade/Device Name: Dynesys® Spinal System
Regulatory Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: NQP
Dated: January 26, 2004
Received: January 28, 2004

Dear Mr. Crabtree:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for the indication of spinal stabilization without fusion have not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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); 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 information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

12.0 Indications Enclosure

510(k) Number (if known): K031611

Device Name: DYNESYS® Spinal System

Indications for Use:

When used as a pedicle screw fixation system in skeletally mature patients, the DYNESYS Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, kyphosis, and failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the DYNESYS Spinal System is indicated for use in patients:

a) Who are receiving fusions with autogenous graft only
b) Who are having the device fixed or attached to the lumbar or sacral spine; and
c) Who are having the device removed after the development of a solid fusion mass.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

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

510(k) Number K031611