APR 18 2006



## 510 (k) Summary of Safety and Effectiveness

Date Summary Prepared: January 3, 2006

Submitter Information: Spinal USA
213 Eastside Lane
Brandon, MS 39047

Contact Name: Jeffrey Johnson
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Device Trade Name: Slimplicity Anterior Cervical Plate System

Common Name: Spinal Intervertebral Body Fixation Orthosis
Anterior Cervical Plate System

Regulatory Number: 888.3060
Classification: Class II
Product Code: KWQ

**INTENDED USE:**
The Slimplicity Anterior Cervical Plate System is indicated for use in the temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with: degenerative disc disease (DDD) (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (including fractures or dislocations); spinal tumors; spinal stenosis; pseudarthrosis; and failed previous fusions.

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

**DEVICE DESCRIPTION:**
The Slimplicity Anterior Cervical Plate System consists of various sizes of anterior cervical bone plates, locking rivets pre-assembled, and bone screws, which can be assembled with associated instruments to provide immobilization of the cervical spine. All components are made from medical grade titanium or titanium alloy described by such standards as ASTM F136 or ISO5832-3. The products are supplied clean and "NON-STERILE".

**EQUIVALENT DEVICE:**

Testing in accordance with ASTM F1717-04 "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model" of the Slimplicity Anterior Cervical Plate System demonstrates that the device is substantially equivalent to the Deltaloc Anterior Cervical Plate System (K993513), Synthes Spine Anterior CSLP System (K030866) and the Reflex Anterior Cervical Plate System (K031702).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Spinal USA
c/o Mr. Jeffrey Johnson
213 Eastside Lane
Brandon, Mississippi 39047

APR 18 2006

Re: K060025
Trade/Device Name: Slimplicity Anterior Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation System
Regulatory Class: II
Product Code: KWQ
Dated: March 22, 2006
Received: March 29, 2006

Dear Mr. Johnson:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/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

# Indications for Use

510(k) Number (if known): K060025

Device Name: Slimplicity Anterior Cervical Plate System

Indications for Use:

The Slimplicity Anterior Cervical Plate System is indicated for use in the temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with: degenerative disc disease (DDD) (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (including fractures or dislocations); spinal tumors; spinal stenosis; pseudarthrosis; and failed previous fusions.

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| Prescription Use ___X___ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K060025