510 (k) Summary of Safety and Effectiveness

K070922

Date Summary Prepared: March 29, 2007

Submitter Information: Spinal USA
644 Lakeland East Drive Suite A
Flowood, MS 39047

SEP 19 2007

Contact Name: Jeffrey Johnson
Phone: 601-420-4244
Fax: 601-420-5501
E-mail: jeff@spinalusa.com

Device Trade Name: Spinal USA Anterior Lumbar Plate System

Common Name: Spinal Fixation System

Regulatory Number: 888.3060

Classification: Class II

Product Code: KWQ

Predicate Devices: Synthes Anterior Tension Band System (K022791)
Aegis Anterior Lumbar Plate System (K052546)
Pyramid Anterior Plate Fixation System (K013665)
UnityLX Anterolateral Lumbar Plate System (K061229)
Trinica Anterior Lumbar Plate System (K061353)

INTENDED USE:
The Spinal USA Anterior Lumbar Plate System is intended for use as an anteriorly placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels. The device is intended as a temporary fixation device until fusion is achieved. The Spinal USA Anterior Lumbar Plate System is intended for anterior lumbar (L1-S1) fixation for the following indications: degenerative disc disease (DDD), defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

DEVICE DESCRIPTION:
The Spinal USA Anterior Lumbar Plate System consists of a range of plate and screw sizes. The plates come in sizes of: 21mm, 23mm, 25mm. The screws come in 5.0mm and 5.5mm diameters and the screw lengths are 25mm, 30mm, 35mm. The plates locking mechanism is a preassembled rivet that is attached to every plate. The plates attach to the anterior or anterolateral aspect of the vertebral body of the lumbar/lumbosacral spine (levels L1-S1) and provide stabilization to permit the biological process of spinal fusion to occur. 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:
Documentation was provided which demonstrated the Spinal USA Anterior Lumbar Plate System to be substantially equivalent to its predicate devices with respect to performance data, intended use and indications, and basic principles of operation. As demonstrated by performance data, these technological differences do not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2007

Spinal USA
% Mr. Jeffery Johnson
Manager, Regulatory Affairs
644 Lakeland East Drive, Suite A
Flowood, Mississippi 39232

Re: K070922
Trade/Device Name: Spinal USA Anterior Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: March 29, 2007
Received: July 18, 2007

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 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) 638-2041 or (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

Indications for Use

510(k) Number : K070922

Device Name: Spinal USA Anterior Lumbar Plate System

Indications for Use:

The Spinal USA Anterior Lumbar Plate System is intended for use as an anteriorly placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels. The device is intended as a temporary fixation device until fusion is achieved. The Spinal USA Anterior Lumbar Plate System is intended for anterior lumbar (L1-S1) fixation for the following indications: degenerative disc disease (DDD), defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 K070922