

510 (k) Summary of Safety and Effectiveness

K092659

Date Summary Prepared: August 27, 2009

Submitter Information: Spinal USA
2050 Executive Drive
Pearl, MS 39208

NOV 17 2009

Contact Name: Jeffrey Johnson
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Device Trade Name: Spinal USA RCS Anterior Buttress Plate System

Common Name: Anterior Buttress Plate System

Regulatory Number: 888.3060-Spinal Intervertebral Body Fixation Orthosis
Classification: Class II
Product Code: KWQ

INTENDED USE:

The Spinal USA RCS Buttress Plate System is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

DEVICE DESCRIPTION:

The Spinal USA RCS Anterior Buttress Plate System is a temporary implant used to prevent allograft or autograft extrusion. The Spinal USA RCS Anterior Buttress Plate System consists of plates and bone screws. The Spinal USA RCS Anterior Buttress Plate System is also intended to provide stabilization and augment development of a solid spinal fusion. The Spinal USA RCS Anterior Buttress Plate System fixates to the anterior portion of the thoracolumbar vertebral body. The construct may be employed alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. The components will be provided non-sterile.

EQUIVALENT DEVICE:

Documentation was provided which demonstrated the Spinal USA RCS Anterior Buttress Plate System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, performance and material of manufacture.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Spinal USA
% Mr. Jeffrey Johnson
Manager of Regulatory Affairs
2050 Executive Drive
Pearl, Mississippi 39208

NOV 17 2009

Re: K092659

Trade/Device Name: Spinal USA RCS Anterior Buttress Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 27, 2009
Received: August 28, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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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 advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



jm Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092659

Device Name: Spinal USA RCS Anterior Buttress Plate System

Indications for Use:

The Spinal USA RCS Anterior Buttress Plate System is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. The device is not intended for load bearing applications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature] for Mark Melkerson
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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