K073437

510(k) Summary: THOR™ Anterior Plating System

Submitter: Stryker Spine
2 Pearl Court
Allendale, New Jersey 07401

FEB 13 2008

Contact Person Mr. Curtis Truesdale
Regulatory Affairs Project Manager
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Date Prepared February 8, 2008

Trade Name Stryker Spine THOR™ Anterior Plating System
Proposed Class Class II
Classification Name and Number Spinal Intervertebral Body Fixation Orthosis
21 CFR 888.3060
Product Code KWQ

Predicate Devices
Synthes Anterior Tension Band System: 510(k) #K022791
Stryker Spine CENTAUR Spinal System: 510(k) #K994347,#K001844
Stryker Spine Xia Stainless Steel System: 510(k) #K012870

Device Description The Stryker Spine THOR™ Anterior Plating System is designed for anterior and anterolateral stabilization of the lumbar and lumbosacral spine (L1-S1). The system consists of a variety of plates and bone screws manufactured from Titanium alloy. The plates have an anatomical shape design and are preassembled with rings to accommodate the insertion of bone screws.

Intended Use	The Stryker Spine THOR™ Anterior Plating System is indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach below the bifurcation of the great vessels. THOR™ Anterior Plating System is intended for use in the lumbar and lumbosacral spine (L1-S1). THOR™ Anterior Plating System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); Pseudoarthrosis; Spondylolysis; Spondylolisthesis; Trauma (i.e., fracture or dislocation); Deformities (i.e. scoliosis or lordosis); Spinal Stenosis; and Failed Previous Fusion.
Summary of the Technological Characteristics	Testing in compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 was performed for the THOR™ Anterior Plating System, and demonstrated equivalent mechanical performance characteristics to the Stryker Spine CENTAUR Spinal System [510(k) K994347, K001844] and Stryker Spine Xia Stainless Steel System [510(k) K012870]. THOR™ system demonstrated equivalent material biocompatibility to the Stryker Spine CENTAUR Spinal System indicated above and is equivalent to the Synthes Anterior Tension Band System [510(k) K022791] with respect to intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2008

Stryker Spine
% Mr. Curtis Truesdale
Regulatory Affairs Project Manager
2 Pearl Court
Allendale, New Jersey 07401

Re: K073437
Trade/Device Name: THOR™ Anterior Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: December 5, 2007
Received: December 6, 2007

Dear Mr. Truesdale:

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 its toll-free number (800) 638-2041 or (240) 276-3150 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): K_____

Device Name: Stryker Spine THOR™ Anterior Plating System

Indications For Use:

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- Pseudoarthrosis;
- Spondylolysis;
- Spondylolisthesis;
- Trauma (i.e., fracture or dislocation);
- Deformities (i.e., scoliosis or lordosis)
- Spinal Stenosis; and
- Failed Previous Fusion.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Burns

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K073437