K080928

Special 510(k) Summary:
Line Extension to the Xia® Spinal System

APR 30 2008

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person:	Curtis Truesdale Regulatory Affairs Project Manager Telephone: (201) 760-8296 Fax: (201) 760-8496
Date of Summary Preparation:	March 19, 2008

Device Identification

Proprietary Name:	Xia® Spinal System
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 Spinal Intervertebral Body Fixation Orthosis 21 CFR §888.3060 Pedicle Screw Spinal System 21 CFR 888.3070 (b) (1) & (b) (2)
Product Codes:	NKB, KWP, KWQ, MNH, MNI

Predicate Device Information: Stryker Spine Xia® Spinal System (K060361, K053115, K013823)

Predicate Device Identification

The Stryker Spine Xia® Spinal System consists of Monoaxial and Polyaxial Screws, Washer, Hooks, Blocker, Rods, Staples, and Connectors. The components are manufactured from either Stainless Steel or Titanium material (Ti alloy and CP Titanium).

Description of Device Modification

This submission is intended to address a line extension to Xia® Spinal System. The line extension includes the addition of Xia Stainless Steel Uni-Planar Screws.

Intended Use:

The Xia® Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indicating: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The 6 mm diameter rods from the DIAPASON™ Spinal System and OPUS™ Spinal System are intended to be used with the other components of the Xia® Titanium Spinal System. The Titanium Multi-axial Cross Connectors are intended to be used with the other components of the Xia® Titanium Spinal System.

Statement of Technological Comparison:

The subject components share the same intended use, material, and basic design concepts as that of the predicate device: Stryker Spine Xia® Spinal System (K060361, K053115 and K013823). Mechanical testing also demonstrated comparable mechanical properties to the predicate device: Stryker Spine Xia® Spinal System (K060361, K053115 and K013823)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 2008

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

Re: K080928
Trade/Device Name: Xia Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWQ, KWP
Dated: April 1, 2008
Received: April 2, 2008

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): _____

Device Name: Xia Spinal System Line Extension - Uniplanar Screws

Indications for Use:

The Xia® Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

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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 K080928