Special 510(k) Summary of Safety and Effectiveness:
Line Extension to the Xia® Spinal System

Proprietary Name:	Xia® Spinal System
Common Name:	Spinal Fixation Appliances
Proposed Regulatory Class:	Class II 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
Device Product Code:	87 KWP: Appliance, Fixation, Spinal Interlaminal 87 KWQ: Appliance, Fixation, Spinal, Intervertebral Body 87 MNH: Spondylolisthesis Spinal Fixation System 87 MNI: Orthosis, Spinal, Pedicle Fixation
For Information contact:	Simona Voic Regulatory Affairs Project Manager 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8145 Fax: (201) 760-8345 Email: Simona.Voic@stryker.com
Date Summary Prepared:	January 5, 2005
Predicate Device Identification:	K002858 Xia Spine System K013823 Xia Spinal System

Predicate Device Description
The Xia Titanium Spinal System consists of Monoaxial and Polyaxial Screws, Washer, Hooks, Blocker, Rods, Connectors, Multi-Axial Cross Connectors (MACs), and Staple. The components are manufactured from Titanium material (Ti alloy and CP Titanium).

Description of Device Modification
The purpose of this submission is to include cannulated polyaxial screws to the Xia® Titanium Spinal System.

Intended Use:

The Xia Spinal System is intended for use in the noncervical spine. When used as a pedicle screw fixation system, the Xia Spinal System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

When used as a pedicle screw fixation system, the Xia Spinal System is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the Xia Spinal System is indicated for patients with degenerative disc disease which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis or revision of failed fusion attempts.

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

Statement of Technological Comparison:

The subject components share the same intended use and basic design concepts as that of the predicate device. Mechanical testing demonstrated comparable mechanical properties to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2005

Ms. Simona Voic
Regulatory Affairs Project Manager
Stryker Spine
2 Pearl Court
Allendale, New Jersey 07401

Re: K043473
Trade/Device Name: Xia® Spinal System
Regulation Number: 21 CFR 888.3050, 21 CFR 888.3060, and 21 CFR 888.3070
Regulation Name: Spinal interlaminal fixation orthosis, Spinal intervertebral body fixation orthosis, and Pedicle screw spinal system
Regulatory Class: II
Product Code: KWP, KWQ, MNH, and MNI
Dated: December 14, 2004
Received: December 16, 2004

Dear Ms. Voic:

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.

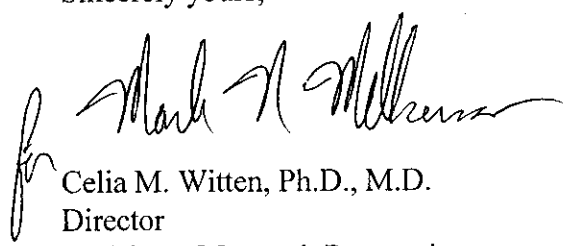
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 se 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-__. 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/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
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): K043473

Device Name: Xia® Spinal System

Indications For Use:

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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)

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

510(k) Number K043473