DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR 23 2009

Re: K083393
Trade/Device Name: Stryker Spine XIA 3 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Names: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWQ, KWP
Dated: January 14, 2009
Received: January 16, 2009

Dear Mr. Truesdale:

This letter corrects the substantially equivalent letter dated April 1, 2009.

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.

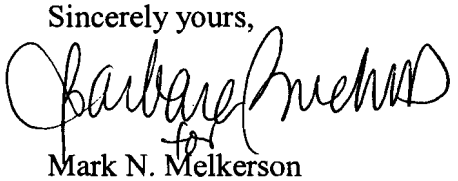
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (if known): K083393
Device Name: Stryker Spine XIA 3 Spinal System – Line Extension

Indications for Use:

The Stryker Spine XIA 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA 3 Spinal 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 (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 Ø5.5 mm rods from the Stryker Spine Radius Spinal System and Ø6.0 mm Vitallium rods from XIA Spinal System are intended to be used with the other components of XIA 3 Spinal System.

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

(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 K083393

K083393
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Special 510(k) Summary of Safety and Effectiveness:
Xia® 3 Spinal System - Line Extension

Proprietary Name:	Xia® 3 Spinal System – Line Extension
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	1) Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 2) Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060 3) Pedicle Screw Spinal System, 21 CFR §888.3070 (b) (1) & (b) (2)
Device Product Code:	NKB, KWP, KWQ, MNH, MNI
Proposed Regulatory Class:	Class III
For Information contact:	Curtis Truesdale Regulatory Affairs Project Manager 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8296 Fax: (201) 760-8496 Email: Curtis.Truesdale@Stryker.com
Date Summary Prepared:	November 14, 2008
Predicate Devices	▪ Stryker Spine Xia® 3 Spinal System, K071373; ▪ Stryker Spine Radius® Spinal System, K062270; ▪ Stryker Spine Xia® II, K013823; ▪ Moss Miami System, K950697;
Description of Device Modification	This 510(k) is intended to introduce an extension to the existing Xia® 3 Spinal System. The proposed line extension includes the addition of various screws, connectors and a hook.

Intended Use	The Xia® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation, the Xia® 3 Spinal 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 (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 Ø5.5mm rods from the Stryker Spine Radius® Spinal System and Ø6.0mm Vitallium rods from Xia® Spinal System are intended to be used with the other components of Xia® 3 Spinal System.
Summary of the Technological Characteristics	Documentation is provided which demonstrates the new components of the Stryker Spine Xia® 3 Spinal System to be substantially equivalent to the predicate devices in terms of material, design, and indications for use. Engineering analysis and testing to demonstrate compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 were completed for the Stryker Spine Xia® 3 Spinal System, including the subject components.