APR 13 2006

# Special 510(k) Summary of Safety and Effectiveness: Line Extension to the Xia® 4.5 Spinal System

## Submission Information

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| Name and Address of the Sponsor of the 510(k) Submission: | Stryker Spine<br>2 Pearl Court<br>Allendale, NJ 07401 |
| Contact Person: | Simona Voic<br>Regulatory Affairs Project Manager<br>Stryker Spine<br>2 Pearl Court, Allendale, NJ 07401<br>Tel: (201) 760 - 8145 |
| Date of Summary Preparation: | March 20, 2006 |

## Device Identification

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|---|---|
| Proprietary Name: | Xia® 4.5 Spinal System |
| Common Name: | Spinal Fixation Appliances |
| Classification Name and Reference: | Spinal Interlaminal Fixation Orthosis,<br>21 CFR §888.3050<br>Spinal Intervertebral Body Fixation Orthosis<br>21 CFR §888.3060<br>Pedicle Screw Spinal System<br>21 CFR §888.3070(b)(1) and (b)(2) |
| Device Product Code: | NKB, KWP, KWQ, MNH, and MNI |

## Predicate Device Information:

K050461, K052761, K060361 – Stryker Spine Xia® 4.5 Spinal System

K962628 – DePuy Spine MOSS Miami™ 4.0 Spinal System

K950697 – Moss Miami 5.0 Spinal System

K020709 – CD Legacy 4.5 Spinal System

**Predicate Device Identification**

The Stryker Spine Xia® 4.5 Spinal System is comprised of Ø 4.5 mm rods, Polyaxial and Monoaxial bone screws, Blockers, Hooks, Dual Staples, and Connectors. The components are available in a variety of diameters and lengths in order to accommodate patient anatomy and are fabricated from titanium alloy. The implants are provided non-sterile and are used for either posterior or anterolateral non-cervical spinal fixation.

**Description of Device Modification**

This submission is intended to address a line extension to Xia® 4.5 Spinal System. The line extension includes:

- A new size dual staple component in both a rostral and a caudal configuration,
- A new polyaxial cross connector in sizes small, medium, large, and extra large, and
- A new longitudinal rod-to-rod connector to join a Ø 4.5 mm rod from the Xia® 4.5 Spinal System to a Ø 6.0 mm rod from the Xia® Spinal System (K013688, K984251), DIAPASON™ Spinal System (K951725), and OPUS™ Spinal System (K993402 & K030369).

**Intended Use:**

The Xia® 4.5 Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (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 Stryker Spine DIAPASON™ Spinal System, Opus™ Spinal System and XIA® Spinal System can be linked to the XIA® 4.5 Spinal System via the rod-to-rod connector.

**Statement of Technological Comparison:**

The subject components share the same intended use, material, and basic design concepts as that of the predicate device: Xia® 4.5 Spinal System (K050461, K052761, and K060361). Mechanical testing also demonstrated comparable mechanical properties to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

Stryker Spine
c/o Ms. Simona Voic
Regulatory Affairs Project Manager
2 Pearl Court
Allendale, NJ 07401

Re: K060748
Trade/Device Name: Xia® 4.5 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, KWP, KWQ, MNH, MNI
Dated: March 20, 2006
Received: March 21, 2006

Dear Ms. Voic:

This letter corrects our substantially equivalent letter of April 14, 2006.

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 (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.

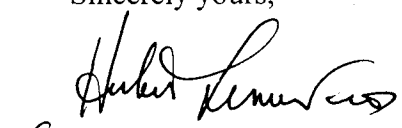
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 continue 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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

# Indications for Use

510(k) Number (if known): K060748

Device Name: Xia® 4.5 Spinal System

Indications For Use:

The Xia® 4.5 Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (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____ 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)

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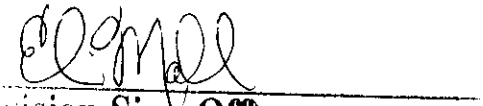
Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K060748