510(K) SUMMARY

JUN 2 2 2012

1.1 Applicant

Stryker Spine
2 Pearl Court.
Allendale, NJ 07401
Phone: (201)-760-8206
Fax: (201)-760-8406
E-mail: tiffani.rogers@stryker.com

Contact Information:

Tiffani Rogers Regulatory Affairs Manager
Stryker Spine
Two Pearl Court
Allendale, NJ 07401
Phone: (201)- 760-8206
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E-mail: tiffani.rogers@stryker.com

1.2 Device Trade Name:

XIA® 4.5 Spinal System

1.3 Device Common Name:

Spinal Fixation Appliances

1.4 Establishment Registration Number

3004024955

1.5 Manufacturer Address

Stryker Spine
Zone Industrielle Demarticot
Cestas, France 33610
Phone: + 33 577 97 08 40
Manufacturer Establishment Number: 9617544

And

Stryker Spine
Le Cret Du Locle 10a
La Chaux De Fonds
Switzerland 2300
Establishment Registration Number: 3005525032

1.6 Device Classification:

Primary Classification - Class: II
Classification: 21 CFR 888.3070 (b) (1) & (b) (2)
Classification Name: Pedicle Screw Spinal System

Additional Classification (K60361, K060979) - Class: II/III
Classification: 21 CFR §888.3060
Classification Name: Pedicle Screw Spinal System, Spinal Intervertebral Body Fixation Orthosis

Additional Classification (K060748) - Class: II/III
Classification: 21 CFR 888.3050
Classification Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis

1.7 Device Product Codes:

OSH, NKB, KWP, KWQ, MNH, MNI

1.8 Device Description/Modification:

The XIA® 4.5 Spinal System consists of a variety of titanium Monoaxial & Polyaxial Bone Screws, Monoaxial & Polyaxial Reduction Screws, Hooks, Blockers, Rods, Rod-to-Rod Connectors, Dual Staples and Connectors. The existing components of the XIA® 4.5 Spinal System were determined substantially equivalent through K050461 for class II indications consistent with 21 CFR 888.3070 (b) (1). The indications were expanded through K060361 to include class III indications per product code NKB, 21 CFR 888.3070 (b) (2). Subsequent line extensions have been cleared through K060748, K060979 and K092605.

The expansion of indications for the XIA 4.5 Spinal System is proposed for the inclusion of adolescent idiopathic scoliosis alone, and not other indications for a pediatric population. As pediatric patients are unlikely to exhibit symptoms of degenerative disc disease (DDD) or stenosis due to the wear and tear on the spine necessary to develop these diseases, expansion of these indications to a pediatric population is not warranted.

1.9 Indications for Use

The XIA® 4.5 Spinal System is intended for anterior/anteriolateral 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® 4.5 Spinal System can be linked to the XIA® 4.5 Spinal System via the rod-to-rod connector.

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA 4.5 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA 4.5 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

1.10 Predicate Devices

- Medtronic Sofamor Danek, CD Horizon Spinal System, K091445 and K102807
- Synthes Spine USS Small Structure System, K994121 and K103287;
- Stryker Spine XIA 4.5 Spinal System, K092605 and K060361;

1.11 Substantial Equivalence

Testing performed on this device indicates that the XIA 4.5 Spinal System is substantially equivalent to predicate devices. Mechanical testing of the system included static and dynamic compression bending testing and static torsion testing per ASTM F1717and interconnection strength testing per ASTM F1798, as well as, a clinical literature analysis.

The XIA 4.5 Spinal System was shown to be substantially equivalent to previously cleared devices with respect to its indications for use, design, function, and materials.

The Xia 4.5 Spinal System substantial equivalence determination to the predicate systems is based on dimensional comparisons and engineering analyses in addition to preclinical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 27, 2013

Stryker Corporation
% Ms. Tiffani Rogers
Regulatory Affairs Manager
2 Pearl Court
Allendale, New Jersey 07401

Re: K121342
Trade/Device Name: Xia® 4.5 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, OSH, KWP, KWQ, MNH, MNI
Dated: May 2, 2012
Received: May 4, 2012

Dear Ms. Rogers:

This letter corrects our substantially equivalent letter of June 22, 2012.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121342

Device Name: XIA® 4.5 Spinal System

Indications for Use:

The XIA® 4.5 Spinal System is intended for anterior/anteriolateral 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® 4.5 Spinal System can be linked to the XIA® 4.5 Spinal System via the rod-to-rod connector when used for the aforementioned indications in skeletally mature patients as an adjunct to fusion.

Except for the staples, the Xia 4.5 Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior noncervical pedicle screw fixation in pediatric patients. The XIA 4.5 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Prescription Use	X	AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)			(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121342