DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 16, 2017

Stryker Corporation
Meriam Gabera, MS, RAC
Associate Manager, Regulatory Affairs
2 Pearl Court
Allendale, New Jersey 07401

Re: K170496
Trade/Device Name: Xia® 3 Spinal System – Serrato, Stryker Spine Power Adaptor Instrument Accessory
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: April 19, 2017
Received: April 20, 2017

Dear Ms. Gabera:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170496

Device Name
Xia® 3 Spinal System - Serrato

Indications for Use *(Describe)*
The Xia® 3 Spinal System is intended for use in the non-cervical spine. When used as an anterior/anterolateral and posterior, non-cervical 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 (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e. fracture of dislocation)
- Spinal stenosis
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudarthrosis
- Failed previous fusion

The 5.5 mm rods from the Stryker Spine Radius™ Spinal System and 6.0 mm Vitallium rods from the Xia® Spinal System are intended to be used with the other components of the Xia® 3 Spinal System.

When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the Xia® 3 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia® 3 Spinal System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170496

Device Name
Stryker Spine Power Adaptor Instrument Accessory

Indications for Use *(Describe)*

Intended Use (Power):
To facilitate the placement of pedicle screws using the power technique (corded and cordless), the use of the Stryker Spine Power Adaptor is intended for exclusive use with the Stryker Instruments Hudson Modified Trinkle Reamer and the Stryker Instruments CD3 Cordless Driver 3 and the Stryker Instruments RemB Universal Driver. When the power adaptors are attached, the CD3 Cordless Driver 3 and RemB Universal Driver provide power (corded and cordless) to rotate screwdrivers for the insertion of pedicle screws.

Pedicle screws from select Stryker Spine implant systems may be implanted in the non-cervical spine using powered (corded and cordless) instrumentation. The systems included are the family of Xia® Spinal Systems (Xia® Stainless Steel, Xia® II, Xia® Anterior, and Xia® Precision), Xia® 3 Spinal System, Xia® 4.5 Spinal System, Radius® Spinal System, Mantis® Spinal System, Mantis® Redux Spinal System, and the ES2® Spinal System.

Indications for Use (Power):
The Xia® Spinal System is intended for anterior/anteriolateral and posterior, non-cervical pedicle and non-pedicle fixation in skeletally mature patients as an adjunct to fusion 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; curvature (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The Xia® 3, RADIUS® Spinal Systems are intended for use in the non-cervical spine. When used as an anterior/ anteriolateral and posterior, non-cervical pedicle and non-pedicle fixation system, the Xia® II, Xia® 3, and Radius® Spinal Systems are 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 Xia® 4.5 Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (i.e. fracture of dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; failed previous fusion.

The Stryker Spine Diapson® 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.

When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the Xia® 3 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia® 3 Spinal System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Except for the staples, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the Xia® 4.5 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia® 4.5 Spinal System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The Mantis® Spinal System, Mantis® Redux Spinal System, and ES2® Spinal System is intended for percutaneous, posterior, non-cervical pedicle and non-pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary as required by 21CFR§807.92(c): Xia® 3 Spinal System – Serrato Line Extension	
Submitter	Stryker Corporation 2 Pearl Court Allendale, NJ 07401
Contact Person	Meriam Gabera, MS, RAC Associate Manager, Regulatory Affairs Phone: 201-749-8043 Fax: 201-831-3000 E-mail: meriam.gabera@stryker.com
Date Prepared	April 19th, 2017
Trade Name	Xia® 3 Spinal System – Serrato Stryker Spine Power Adaptor Accessory
Common Name	Pedicle Screw Spinal System
Proposed Class	Class II
Classification Name, Codification	• Pedicle Screw Spinal System, 21 CFR § 888.3070 (b)(1) & (b)(2) • Spinal Intervertebral Body Fixation Orthosis, 21 CFR § 888.3060 • Spinal Interlaminal Fixation Orthosis, 21 CFR § 888.3050
Product Codes	NKB, KWP, KWQ
Predicate Devices	**Primary Predicate:** • Xia® 3 Spinal System - K142381 **Additional Predicates:** • Xia® 4.5 Spinal System - K152632 • CD Legacy (Horizon) - K020709 • Moss Miami - K950697 • Radius® Spinal System - K101144 • Stryker Spine Power Adaptor Instrument Accessory – K152632
Device Description	The Xia® 3 Spinal System is an orthopedic spinal system comprised a variety of shapes and sizes of screws, blockers, and hooks that affix several different types of rods and connectors to vertebrae of the spinal column for the purposes of stabilization, or corrective action through the application of force. The system can be rigidly locked into a range of configurations specific to each patient. The Xia® 3 Serrato Line

	Extension introduces new dual lead screws, with an enhanced cutting flute (also referred to as serrations), offered in the following configurations: Polyaxial Screws, Medial BA Polyaxial Screws, Reduction Polyaxial Screws, and Cannulated Polyaxial Screws. The Xia® 3 Spinal System, including the new Serrato bone screws, will continue to be used with the Stryker Spine Power Adaptor Accessory Instrument, Stryker Instruments Hudson Modified Trinkle Reamer, the CD3 Cordless Driver 3 System, and the RemB Universal Driver, to facilitate the insertion of the pedicle screws. The adaptors serve as a mechanical interface between the power drivers and screwdriver instruments. When the adaptor is attached to the Hudson Modified Trinkle Reamer, the RemB Corded driver or the CD3 Cordless Driver 3 provides appropriate power to rotate the screw drivers for the insertion of the pedicle screws. The accessory indications for use were updated to reflect the indications for use of the Xia® 3 Spinal System.
Intended use and Indications for Use for the Xia® 3 Spinal System	The Xia® 3 Spinal System is intended for use in the non-cervical spine. When used as an anterior/anterolateral and posterior, non-cervical 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 (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies) • Spondylolisthesis • Trauma (i.e. fracture of dislocation) • Spinal stenosis • Curvatures (i.e., scoliosis, kyphosis, and/or lordosis) • Tumor • Pseudarthrosis • Failed previous fusion

	The 5.5 mm rods from the Stryker Spine Radius™ Spinal System and 6.0 mm Vitallium rods from the Xia® Spinal System are intended to be used with the other components of the Xia® 3 Spinal System. When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the Xia® 3 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia® 3 Spinal System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.
Intended use and Indications for Use with the Power Adaptor Instrument Accessory	Intended Use (Power): To facilitate the placement of pedicle screws using the power technique (corded and cordless), the use of the Stryker Spine Power Adaptor is intended for exclusive use with the Stryker Instruments Hudson Modified Trinkle Reamer and the Stryker Instruments CD3 Cordless Driver 3 and the Stryker Instruments RemB Universal Driver. When the power adaptors are attached, the CD3 Cordless Driver 3 and RemB Universal Driver provide power (corded and cordless) to rotate screwdrivers for the insertion of pedicle screws. Pedicle screws from select Stryker Spine implant systems may be implanted in the non-cervical spine using powered (corded and cordless) instrumentation. The systems included are the family of Xia® Spinal Systems (Xia® Stainless Steel, Xia® II, Xia® Anterior, and Xia® Precision), Xia® 3 Spinal System, Xia® 4.5 Spinal System, Radius® Spinal System, Mantis® Spinal System, Mantis® Redux Spinal System, and the ES2® Spinal System. Indications for Use (Power):

	The Xia® Spinal System is intended for anterior/anteriolateral and posterior, non-cervical pedicle and non-pedicle fixation in skeletally mature patients as an adjunct to fusion 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; curvature (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The Xia® 3, RADIUS® Spinal Systems are intended for use in the non-cervical spine. When used as an anterior/anteriolateral and posterior, non-cervical pedicle and non-pedicle fixation system, the Xia® II, Xia® 3, and Radius® Spinal Systems are 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 Xia® 4.5 Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (i.e. fracture of dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; failed previous fusion. The Stryker Spine Diapson® 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.

	When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the Xia® 3 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia® 3 Spinal System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. Except for the staples, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the Xia® 4.5 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia® 4.5 Spinal System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. The Mantis® Spinal System, Mantis® Redux Spinal System, and ES2® Spinal System is intended for percutaneous, posterior, non-cervical pedicle and non-pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion 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.

Summary of Technological Characteristics	The Xia® 3 Spinal System shares the same materials, fundamental scientific technologies and similar design as the predicate device. The Xia® 3 bone screws are also intended to be inserted manually or under power (cordless and corded) utilizing the CD3 Cordless Driver 3 or the RemB Universal Driver hand held devices. Both drivers connect to the screwdriver via the Hudson Modified Trinkle Reamer which mates to the Stryker Spine Power Adaptor. The power adaptor accessory instrument assembly aids in the rotation of the bone screw to facilitate insertion. No changes were made to the existing power adaptor accessory instruments to accommodate the subject device.
Summary of Performance Data	The Xia® 3 Spinal System has demonstrated substantial equivalence to the predicate device. Engineering analysis and applicable ASTM testing completed on the subject system demonstrate compliance with FDA's Guidance for Spinal System 510(k) May 3, 2004. The following mechanical tests were performed: • Static Compression (per ASTM F1717-15) • Static Torsion (per ASTM F1717-15) • Dynamic Compression Bending (ASTM F1717-15) • Axial Gripping Capacity (per ASTM F1798-13) • Axial Torque Gripping Capacity (per ASTM F1798-13) • Flexion – Extension (per ASTM F1798-13) • Axial Pull Out (per ASTM F2193-14 / ASTM F543-13) • On Axis Tightening Torque
Conclusion	Based upon the analysis of the design features, the use of established well-known materials, feature comparisons, the identical indications for use, and the results of the mechanical and characterization testing, the Xia® 3 Spinal System has demonstrated substantial equivalence to the identified predicate device system.