



April 23, 2020

Stryker Spine
Megan Callanan
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K200666

Trade/Device Name: Stryker Xia 3 Power Adaptor
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: March 11, 2020
Received: March 13, 2020

Dear Megan Callanan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'Neill, MBE
Acting Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K200666

Device Name
Xia 3 Power Adaptor

Indications for Use (Describe)

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/anteriolateral 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 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.

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: Xia 3 Power Adaptor	
Submitter:	Stryker Spine
Contact Person :	Name: Megan Callanan Phone: (551)262-2429 Email: megan.callanan1@stryker.com
Date Prepared:	3/11/2020
Trade Name:	Xia 3 Power Adaptor
Common Name:	Spinal Fixation Appliances, Instrument Accessory
Proposed Class:	Class II
Classification Name:	Thoracolumbosacral Pedicle Screw System
Regulation Number:	888.3070
Product Code:	NKB
Predicate Device:	Primary Predicate is the most recently cleared system K172724. Additional Predicate: K170496, K152632, K120434, K122845, K111478
Device Description:	<p>This special 510(k) premarket notification is to expand the intended use of the Xia 3 Power Adaptor.</p> <p>The Xia 3 Power Adaptor instrument accessory is intended to facilitate the insertion of pedicle screws using powered instrumentation. To facilitate the insertion of pedicle screws using the power technique, the use of the Xia 3 Power Adaptor is intended for use with Stryker power system drivers (corded and cordless). The adaptor serves as a mechanical interface between the power driver and screwdriver instrument. When the adaptor is attached, the driver (corded and cordless) provides appropriate power to rotate screw drivers for the insertion of pedicle screws. No changes have been made to the indications for use of the associated thoracolumbar spinal implant systems 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. The indications for use of each spinal system remain consistent with their most recent 510(k) clearance.</p>
Intended Use	<p>The intended use for the Xia 3 Power Adaptor is to facilitate the placement of pedicle screws using the power technique (corded and cordless), the use of the Xia 3 Power Adaptor is intended for exclusive use with the Stryker Cordless and Coded Power Drivers. When the power adaptors are attached, the Stryker Power Drivers (corded and cordless) provide power to rotate screwdrivers for the insertion of pedicle screws.</p> <p>Pedicle screws from select Stryker Spine implant systems may be implanted in the non-cervical spine using powered (corded and cordless) instrumentation. The</p>

	<p>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.</p>
<p>Indications for Use:</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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,</p>

	<p>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.</p> <p>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.</p> <p>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.</p>
<p>Summary of the Technological Characteristics</p>	<p>The Xia 3 Power Adaptor shares the same materials, fundamental scientific technologies and design as the predicate device.</p> <p>The screws are also intended to be inserted manually or with Stryker’s corded and cordless power drivers. The power adaptor accessory instrument assembly aids in the rotation of the bone screw to facilitate insertion.</p>
<p>Non-Clinical Performance Evaluation</p>	<p>The Xia 3 Power Adaptor Instrument has demonstrated substantial equivalence to the predicate device. Engineering analysis demonstrated connection of the Xia 3 Power Adaptor to various Stryker Power Drivers does not represent a new worse case or affect the performance of the Xia 3 Power Adaptor.</p>
<p>Conclusion</p>	<p>Based on the design features, the use of established well known materials, feature comparisons, and indications for use the subject devices have demonstrated substantial equivalence to the identified predicate devices.</p>