



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

Stryker Corporation  
Ms. Soraya King  
Regulatory Affairs Project Manager  
2 Pearl Court  
Allendale, New Jersey 07401

December 2, 2015

Re: K152632

Trade/Device Name: XIA<sup>®</sup> 4.5 Spinal Fixation System,  
Power Adaptor Instrument Accessory  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class III  
Product Code: NKB, OSH, MNH, MNI, KWP, KWQ  
Dated: September 14, 2015  
Received: September 16, 2015

Dear Ms. King:

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 Parts 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 yours,

**Mark N. Melkerson -S**

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

Enclosure

### Indications for Use

510(k) Number (if known)

K152632

Device Name

XIA® 4.5 Spinal Fixation System

#### Indications for Use (Describe)

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.

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.

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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**Indications for Use**

510(k) Number (if known)

K152632

Device Name  
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/anterolateral 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; pseudarthrosis; and failed previous fusion.

The XIA® 3, RADIUS® Spinal Systems are 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® 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; pseudarthrosis; 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 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, 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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<b>XIA<sup>®</sup> 4.5 Spinal Fixation System</b>	
Submitter	Stryker Corporation 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Soraya King Regulatory Affairs Project Manager  Phone: 201-749-8296 Email: Soraya.King@stryker.com
Date	November 23, 2015
Trade Name	1. XIA <sup>®</sup> 4.5 Spinal Fixation System 2. Power Adaptor Instrument Accessory
Proposed Class	Class III
Classification Name and Number	Pedicle Screw Spinal System, 21 CFR 888.3070
Product Code	NKB, OSH, MNH, MNI, KWP, KWQ
Predicate Devices	<p>1. The XIA<sup>®</sup> 4.5 Spinal Fixation Systems was shown to be substantially equivalent to the devices listed below:</p> <p style="text-align: center;"><u>Primary Predicate</u></p> <ul style="list-style-type: none"> <li>• Stryker Spine XIA<sup>®</sup> 4.5 Spinal System, K142381</li> </ul> <p style="text-align: center;"><u>Additional Predicates</u></p> <ul style="list-style-type: none"> <li>• Stryker Spine XIA<sup>®</sup> 4.5 Spinal System (K140276, K133188, K121342, K060361)</li> <li>• Medtronic CD Legacy (Horizon), K020709</li> <li>• DePuy Motech Moss Miami, K950697</li> <li>• Stryker Spine RADIUS<sup>®</sup> Spinal System, K101144</li> <li>• Stryker Spine XIA<sup>®</sup> 3 Spinal System, K142381</li> </ul> <p>2. The Stryker Spine Power Adaptor Instrument Accessory was shown to be substantially equivalent to the device listed below:</p> <p style="text-align: center;"><u>Additional Predicate</u></p> <ul style="list-style-type: none"> <li>• Stryker Spine Power Adaptor Instrument Accessory, K120434</li> </ul>
Device Description	1. The XIA <sup>®</sup> 4.5 Spinal System is comprised of monoaxial and polyaxial bone and reduction screws, hooks, dual staples, and blockers that affix rods, rod-to-rod connectors, growth connectors, and cross connectors to vertebrae of the spinal column. This submission will introduce new cannulated and

<b>XIA<sup>®</sup> 4.5 Spinal Fixation System</b>	
	<p>non-cannulated polyaxial screws, dual lead self-tapping cortical thread screws, a blocker, top loading rod-to-rod connectors, angled side/top loading connectors, and transition rods.</p> <p>The new XIA<sup>®</sup> 4.5 components consist of additional polyaxial diameter screws (Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø 6.5, Ø8.5 and Ø9.5) in cannulated and non-cannulated designs in various lengths (20mm – 100mm), a blocker, and a new transition rod. The new components will be used in the same manner as the existing predicate XIA<sup>®</sup> 4.5 Spinal System.</p> <p>2. The XIA<sup>®</sup> 4.5 Spinal System 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<sup>®</sup> 4.5 Spinal System.</p>
Intended Use and Indications for Use for the XIA <sup>®</sup> 4.5 Spinal System	<p>The XIA<sup>®</sup> 4.5 Spinal System is intended for anterior/anteriolateral and posterior, non-cervical pedicle and non-pedicle fixation for the following indications:</p> <p>Degenerative Disc Disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)</p> <ul style="list-style-type: none"> <li>• Spondylolisthesis</li> <li>• Trauma (i.e. fracture of dislocation)</li> <li>• Spinal Stenosis</li> <li>• Curvatures (i.e. scoliosis, kyphosis, and/or lordosis)</li> <li>• Tumor</li> <li>• Pseudarthrosis</li> <li>• Failed Previous Fusion</li> </ul> <p>The Stryker Spine DIAPASON<sup>®</sup> Spinal System, Opus<sup>®</sup> Spinal System, and XIA<sup>®</sup> 4.5 Spinal System can be linked to the XIA<sup>®</sup> 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>

<b>XIA<sup>®</sup> 4.5 Spinal Fixation System</b>	
	<p>Except for the staples, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the XIA<sup>®</sup> 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<sup>®</sup> 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>Indications &amp; Intended Use with Power Adaptor Instrument Accessory</p>	<p><b>Intended Use:</b> 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.</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 systems included are the family of XIA<sup>®</sup> Spinal Systems (XIA<sup>®</sup> Stainless Steel, XIA<sup>®</sup> II, XIA<sup>®</sup> Anterior, and XIA<sup>®</sup> Precision), XIA<sup>®</sup> 3 Spinal System, XIA<sup>®</sup> 4.5 Spinal System, Radius<sup>®</sup> Spinal System, MANTIS<sup>®</sup> Spinal System, MANTIS<sup>®</sup> Redux Spinal System, and the ES2<sup>®</sup> Spinal System.</p> <p><b>Indications for Use:</b> The XIA<sup>®</sup> 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>

### **XIA<sup>®</sup> 4.5 Spinal Fixation System**

The XIA<sup>®</sup> 3, RADIUS<sup>®</sup> Spinal Systems are 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<sup>®</sup> II, XIA<sup>®</sup> 3, and RADIUS<sup>®</sup> 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<sup>®</sup> 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 DIAPASON<sup>®</sup> Spinal System, OPUS<sup>®</sup> Spinal System, and XIA<sup>®</sup> 4.5 Spinal System can be linked to the XIA<sup>®</sup> 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, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the XIA<sup>®</sup> 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<sup>®</sup> 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.

<b>XIA<sup>®</sup> 4.5 Spinal Fixation System</b>	
	<p>The MANTIS<sup>®</sup> Spinal System, MANTIS<sup>®</sup> Redux Spinal System, and ES2<sup>®</sup> 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>
Summary of the Technological Characteristics	<p>1. The subject XIA<sup>®</sup> 4.5 Spinal System shares the same materials, geometries, and fundamental scientific technologies as the predicate XIA<sup>®</sup> 4.5 Spinal System.</p> <p>2. The XIA<sup>®</sup> 4.5 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.</p>
Summary of Non-Clinical Testing / Performance Data	<p>The Stryker Spine XIA<sup>®</sup> 4.5 Spinal Systems, with the incorporation of the subject components, has demonstrated substantial equivalence to the predicate device. Engineering analysis and applicable ASTM testing to demonstrate compliance with FDA's Guidance for Spinal System 510(k) May 3, 2004 were completed for the systems. The following mechanical and characterization tests were performed:</p> <ol style="list-style-type: none"> <li>1. <ul style="list-style-type: none"> <li>• Static Compression (per ASTM F1717-14)</li> <li>• Static Torsion (per ASTM F1717-14)</li> <li>• Dynamic Compression Bending (ASTM F1717-14)</li> <li>• Axial Pull Out Strength (per ASTM F2193-14 / ASTM F543-13)</li> <li>• Flexion – Extension (per ASTM F1798-13)</li> <li>• Axial Gripping (per ASTM F1798-13)</li> <li>• Axial Torque Gripping (per ASTM F1798-13)</li> <li>• Axis Tightening Torque</li> </ul> </li> <li>2. <ul style="list-style-type: none"> <li>• Power Screw Insertion - Cadaveric Validation Study</li> </ul> </li> </ol>

<b>XIA<sup>®</sup> 4.5 Spinal Fixation System</b>	
Conclusion	Based on the design features, the use of established well-known materials, feature comparisons, indications for use, and results of the mechanical and characterization testing, the subject devices have demonstrated substantial equivalence to the identified predicate devices.