June 8, 2023

Stryker Spine
Sierra Mertz
Staff Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K222684
Trade/Device Name: XIA® 4.5 Spinal System, XIA® 4.5 Cortical Trajectory, XIA® 3 Spinal System, Serrato® Spinal System, XIA® Growth Rod Conversion Set, XIA® II Spinal System, XIA® Precision System, XIA® Anterior, Diapason® Spinal System, Opus™ Spinal System, Radius® Spinal System, Mantis® Spinal System, Mantis® Redux, Trio® & Trio+ Spinal Fixation System, ES2™ Spinal System, ES2™ Augmentable Spinal System, Oasys® Occipito-Cervico-Thoracic System, Nile® Proximal Fixation Spinal System, Nile® Alternative Fixation Spinal System, and Escalate® Laminoplasty System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWQ, KWP, PGM, NKG, OWI, NQW
Dated: May 11, 2023
Received: May 12, 2023

Dear Sierra Mertz:

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 -S

Colin O'Neill, M.B.E.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
XIA® 4.5 Spinal 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 XlA® 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
Xia® 4.5 Cortical Trajectory

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 XlA® 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
Xia® 3 Spinal System

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 auto graft 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
Xia® 3 Serrato® Spinal System

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 auto graft 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
Xia® Growth Rod Conversion Set

Indications for Use *(Describe)*

he Xia® Growth Rod Conversion Set is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The Xia® Growth Rod Conversion Set may be used with any cleared Xia® 4.5 Spinal System rod construct. The Xia® Growth Rod Conversion Set is not intended for use in conjunction with staples.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
Xia® II Spinal System

Indications for Use *(Describe)*

The Xia® and Xia II Titanium Spinal Systems are intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative-disc disease (DOD) (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 6 mm diameter rods from the DIAPASON™ Spinal System and OPUS™ Spinal System are intended to be used with the other components of the Xia and Xia II Titanium Spinal Systems. The Titanium Multi-Axial Cross Connectors are intended to be used with the other components of the Xia and Xia II Titanium Spinal Systems.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
Xia® Precision System

Indications for Use *(Describe)*

The Xia® Titanium Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative-disc disease (DOD) (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 6 mm diameter rods from the DIAPASON™ Spinal System and OPUS™ Spinal System are intended to be used with the other components of the Xia Titanium Spinal System. The Titanium Multi-Axial Cross Connectors are intended to be used with the other components of the XiaTitanium Spinal Systems.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
Xia® Anterior

Indications for Use *(Describe)*

The Xia® Titanium Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative-disc disease (DOD) (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 6 mm diameter rods from the DIAPASON™ Spinal System and OPUS™ Spinal System are intended to be used with the other components of the Xia Titanium Spinal System. The Titanium Multi-Axial Cross Connectors are intended to be used with the other components of the Xia Titanium Spinal Systems.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
DIAPASON Spinal System

Indications for Use *(Describe)*

The 6mm diameter rods from the DIAPASON Spinal System are intended to be used with the components of the XIA Titanium Spinal System. As a posterior, non-pedicle screw system of the T4-S2 spine, the Diapason Spinal system is indicated for long and short curve scoliosis, vertebral fracture or dislocation, spondylolisthesis, degenerative-disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), previously failed fusion and spinal tumor. When used as a pedicle screw fixation system of the non-cervical spine in skeletally mature patients, the Diapason Spinal system is indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).
In addition, the Diapason Spinal System is indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grade 3 and 4) at the L5-S1 joint, having fusions with autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below) with removal of the implants after the development of a solid fusion mass.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
Opus™ Spinal System

Indications for Use *(Describe)*

The OPUS™ Spinal System is intended for posterior, noncervical 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: 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 OPUS™ Spinal System is also intended to be used in conjunction with the titanium hooks from the OSS/Diapason Spinal System and the Xia Spinal System. The OPUS Spinal System is also intended to be used in conjunction with the Multi-Acis Cross Connectors.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
Radius® Spinal System

Indications for Use *(Describe)*

The Radius® Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the Radius® 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 (DOD) (defined as back pain of discogenic origin with degeneration of the disc confimned by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e. fracture or dislocation);
- Spinal Stenosis;
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthorisis;
- and Failed Previous Fusion

The Radius® Spinal System can also be linked to the XIA® Titanium Spinal System via the 05.5mm to 06.0mm Radius® rod-to-rod connector.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
MANTIS® Redux Spinal System

Indications for Use *(Describe)*

The MANTIS® Redux 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;
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthorisis; 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
MANTIS® Spinal System

Indications for Use *(Describe)*

The MANTIS® 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;
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthorisis; 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
Trio® and Trio + Spinal Fixation Systems

Indications for Use *(Describe)*

The Stryker Spine TRIO® Spinal System is intended for posterior. noncervical pedicle and nonpedicle 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 (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;
- Pseudoarthorisis;
- and Failed Previous Fusion

The TRIO® Spinal Fixation System is intended to be used in conjunction with the OSS Diapason Rods, Opus Spinal System Rods. and the Multi-Axis Cross Connectors. The TRIO®+ Spinal System is intended to be used in conjunction with the OSS/Diapason Rods or Opus Rods, XIA® Pre-bent Rods, and the Multi-Axis Cross Connectors.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
ES2™ Spinal System

Indications for Use *(Describe)*

The ES2™ Spinal System is intended for percutaneous, posterior, non-cervical pedicle and nonpedicle fixation of the pine to provide immobilization and stabilization of spinal segment 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.

The Titanium and Vitallium® rods from the Stryker Spine RADIUS®; MANTIS® and MANTIS® Redux Spinal Systems are intended to be used with the other components of the ES2™ Spinal System.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
ES2 ® Augmentable Spinal System

Indications for Use *(Describe)*

When used without cement, the ES2® Augmentable Spinal System is intended for posterior, non-cervical fixation 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, tumor and/or trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), pseudarthrosis, and/or failed previous fusion.

When used in conjunction with the Vertaplex® HV High Viscosity Radiopaque Bone Cement, the ES2® Augmentable Spinal System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. ES2® Augmentable Spinal System augmented with the Vertaplex® HV High Viscosity Radiopaque Bone Cement is for use at spinal levels where the structural integrity of the spine is not severely compromised.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
OASYS® System

Indications for Use *(Describe)*

The Stryker Spine OASYS® System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (Tl-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The Stryker Spine OASYS® System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The Stryker Spine OASYS® System can be linked to the Xia® System, SR90D System and Xia® 4.5 Spinal System via the rod-to-rod connectors and transition rods.

The Stryker Spine OASYS® System can also be linked to the polyaxial screws of the Xia® II and Xia® 3 Systems via the saddle connector.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
NILE Proximal Fixation Spinal System

Indications for Use *(Describe)*

The NILE Proximal Fixation Spinal System are temporary implants for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:
1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The NILE Proximal Fixation Spinal System may also be used in conjunction with other medical implants made of similar metals whenever 'wiring' may help secure the attachment of other implants.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
NILE Alternative Fixation Spinal System

Indications for Use *(Describe)*

The NILE Alternative Fixation Spinal System are temporary implants for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:
1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The NILE Alternative Fixation Spinal System may also be used in conjunction with other medical implants made of similar metals whenever 'wiring' may help secure the attachment of other implants.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222684

Device Name
Escalate™ Laminoplasty System

Indications for Use *(Describe)*
The Escalate™ Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The system is intended to hold the lamina open following a laminoplasty procedure.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary	
Submitter:	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person :	Name: Sierra Mertz Phone: (484) 408-8221 Email: sierra.mertz@stryker.com
Date Prepared:	May 09, 2023
Trade Name:	1. XIA® 4.5 Spinal System 2. XIA® 4.5 Cortical Trajectory 3. XIA® 3 Spinal System 4. Serrato® Spinal System 5. XIA® Growth Rod Conversion Set 6. XIA® II Spinal System 7. XIA® Precision System 8. XIA® Anterior 9. Diapason® Spinal System 10. Opus™ Spinal System 11. Radius® Spinal System 12. Mantis® Spinal System 13. Mantis® Redux 14. Trio® & Trio+ Spinal Fixation System 15. ES2™ Spinal System 16. ES2™ Augmentable Spinal System 17. Oasys® Occipito-Cervico-Thoracic System 18. Nile® Proximal Fixation Spinal System 19. Nile® Alternative Fixation Spinal System 20. Escalate® Laminoplasty System
Common Name:	1. XIA® 4.5 Spinal System Pedicle Screw System 2. XIA® 4.5 Cortical Trajectory Pedicle Screw System 3. XIA® 3 Spinal System Pedicle Screw System 4. XIA 3® Serrato® Spinal System Pedicle Screw System 5. XIA® Growth Rod Conversion Set Growing Rod System 6. XIA® Spinal System (Xia II) Pedicle Screw System 7. XIA® Precision System Pedicle Screw System 8. XIA® Anterior Pedicle Screw System 9. Diapason® Spinal System Pedicle Screw System

510(k) Summary	
	10. Opus™ Spinal System Pedicle Screw System 11. Radius® Spinal System Pedicle Screw System 12. Mantis® Spinal System Pedicle Screw System 13. Mantis® Redux Pedicle Screw System 14. Trio® & Trio+ Spinal Fixation System Pedicle Screw System 15. ES2® Spinal System Pedicle Screw System 16. ES2® Augmentable Spinal System Pedicle Screw System 17. Oasys® Occipito-Cervico-Thoracic System Occipito-Cervico-Thoracic Screw System 18. Nile® Proximal Fixation Spinal System Bone fixation cerclage 19. Nile® Alternative Fixation Spinal System Bone fixation cerclage 20. Escalate® Laminoplasty System Spinal Interlaminal Fixation Orthosis
Classification:	Class II
Product code and Classification Name:	1. XIA® 4.5 Spinal System **NKB** - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070 **KWQ** - Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060 **KWP** - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 2. XIA® 4.5 Cortical Trajectory **NKB** - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070 **KWQ** - Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060 **KWP** - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 3. XIA® 3 Spinal System **NKB** - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070 **KWQ** - Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060 **KWP** - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 4. Xia® 3 Serrato® Spinal System **NKB** - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070 **KWQ** - Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060 **KWP** - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 5. XIA® Growth Rod Conversion Set **PGM** – Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070 6. XIA® II Spinal System **NKB** - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070

510(k) Summary

KWQ - Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060
KWP - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050

7. XIA® Precision System
NKB - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070
KWQ - Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060
KWP - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050

8. XIA® Anterior
NKB - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070
KWQ - Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060
KWP - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050

9. Diapason® Spinal System
NKB - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070
KWQ - Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060
KWP - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050

10. Opus Spinal System
NKB - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070
KWQ - Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060
KWP - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050

11. Radius® Spinal System
NKB - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070
KWQ - Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060
KWP - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050

OSH - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070

12. Mantis® Spinal System
NKB - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070
KWQ - Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060
KWP - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050

OSH - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070

13. Mantis® Redux
NKB - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070
KWQ - Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060
KWP - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050

510(k) Summary	
	OSH - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070 14. Trio® & Trio+ Spinal Fixation System **NKB** - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070 **KWQ** - Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060 **KWP** - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 **OSH** - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070 15. ES2® Spinal System **NKB** - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070 **KWP** - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 16. ES2® Augmentable Spinal System **NKB** - Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070 17. Oasys® Occipito-Cervico-Thoracic System **NKG** - Posterior cervical screw system, 21 CFR §888.3075 **KWP** - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 18. Nile® Fixation Spinal System **OWI** - Bone fixation cerclage, 21 CFR §888.3010 19. Nile® Alternative Fixation Spinal System **OWI** - Bone fixation cerclage, 21 CFR §888.3010 20. Escalate® Laminoplasty System **NQW** - Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050
Predicate Devices:	**Primary Predicate:** XIA® 4.5 Spinal System (K172724) **Additional Predicates:** -XIA® 3 Spinal System – Serrato (K170496) -XIA® Growth Rod Conversion Set (K142114) -XIA® Titanium Spinal System (K061854) -MANTIS®, MANTIS® Redux, Radius®, TRIO®& TRIO® +, TRIO® Trauma, XIA®, XIA® 3 and XIA® 4.5 (K133188) -ES2® Spinal System (K122845) -ES2® Augmentable Spinal System (K192818) -OASYS® System (K151755) -NILE Proximal Fixation Spinal System (K161332) -NILE Alternative Fixation Spinal System (K160208) -Escalate® Laminoplasty System (K113802) -EVEREST Spinal System, RANGE (MESA and DENALI) Spinal System, CASPIAN OCT (MESA Mini and DENALI Mini) Spinal System, YUKON OCT Spinal System (K181603)

510(k) Summary	
Device Description:	The subject devices consist of a variety of multiple component spinal fixation systems intended for use as an adjunct to fusion. These devices have been previously cleared by FDA. The primary purpose of this submission is to establish an MR Conditional labeling claim for these implants.
Indications for Use	**XIA® 4.5 Spinal System** 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 XlA® 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. **XIA® 4.5 Cortical Trajectory** 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

510(k) Summary

- Pseudarthrosis
- Failed Previous Fusion

The Stryker Spine DIAPASON® Spinal System, Opus® Spinal System, and XlA® 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.

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 auto graft 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.

510(k) Summary

Pediatric pedicle screw fixation is limited to a posterior approach.

XIA 3® Serrato® 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 auto graft 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.

XIA® Growth Rod Conversion Set

he Xia® Growth Rod Conversion Set is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The Xia® Growth Rod Conversion Set may be used with any cleared Xia® 4.5 Spinal System rod construct. The Xia® Growth Rod Conversion Set is not intended for use in conjunction with staples.

XIA® II Spinal System

510(k) Summary	
	The Xia® and Xia II Titanium Spinal Systems are intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative-disc disease (DOD) (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 6 mm diameter rods from the DIAPASON™ Spinal System and OPUS™ Spinal System are intended to be used with the other components of the Xia and Xia II Titanium Spinal Systems. The Titanium Multi-Axial Cross Connectors are intended to be used with the other components of the Xia and Xia II Titanium Spinal Systems. **XIA® Precision System** The Xia® Titanium Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation 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; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion. The 6 mm diameter rods from the DIAPASON™ Spinal System and OPUS™ Spinal System are intended to be used with the other components of the Xia Titanium Spinal System. The Titanium Multi-Axial Cross Connectors are intended to be used with the other components of the Xia Titanium Spinal Systems. **XIA® Anterior** The Xia® Titanium Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative-disc disease (DOD) (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 6 mm diameter rods from the DIAPASON™ Spinal System and OPUS™ Spinal System are intended to be used with the other components of the Xia Titanium Spinal System. The Titanium Multi-Axial Cross Connectors are intended to be used with the other components of the Xia Titanium Spinal Systems. **Diapason™ Spinal System** The 6mm diameter rods from the DIAPASON Spinal System are intended to be used with the components of the XIA Titanium Spinal System. As a

510(k) Summary	
	posterior, non-pedicle screw system of the T4-S2 spine, the Diapason Spinal system is indicated for long and short curve scoliosis, vertebral fracture or dislocation, spondylolisthesis, degenerative-disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), previously failed fusion and spinal tumor. When used as a pedicle screw fixation system of the non-cervical spine in skeletally mature patients, the Diapason Spinal system is indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). In addition, the Diapason Spinal System is indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grade 3 and 4) at the L5-S1 joint, having fusions with autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below) with removal of the implants after the development of a solid fusion mass. **Opus™ Spinal System** The OPUS™ Spinal System is intended for posterior, noncervical 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: 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 OPUS™ Spinal System is also intended to be used in conjunction with the titanium hooks from the OSS/Diapason Spinal System and the Xia Spinal System. The OPUS Spinal System is also intended to be used in conjunction with the Multi-Acis Cross Connectors. **Radius® Spinal System** The Radius® Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the Radius® 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 (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);

510(k) Summary

- Tumor;
- Pseudoarthorisis;
- and Failed Previous Fusion

The Radius® Spinal System can also be linked to the XIA® Titanium Spinal System via the 05.5mm to 06.0mm Radius® rod-to-rod connector.

MANTIS® Spinal System

The MANTIS® Spinal System and MANIS® Redux 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;
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthorisis; and
- Failed Previous Fusion

MANTIS® Redux Spinal System

The MANTIS® Spinal System and MANIS® Redux 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;
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthorisis; and
- Failed Previous Fusion

Trio/ Trio + ® Spinal Fixation Systems

The Stryker Spine TRIO® Spinal System is intended for posterior, noncervical pedicle and nonpedicle 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:

510(k) Summary

- 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 TRIO® Spinal Fixation System is intended to be used in conjunction with the OSS Diapason Rods, Opus Spinal System Rods. and the Multi-Axis Cross Connectors.

The TRIO®+ Spinal System is intended to be used in conjunction with the OSS/Diapason Rods or Opus Rods, XIA® Pre-bent Rods, and the Multi-Axis Cross Connectors.

ES2 Spinal System

The ES2™ Spinal System is intended for percutaneous, posterior, non-cervical pedicle and nonpedicle fixation of the spine to provide immobilization and stabilization of spinal segment 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.

The Titanium and Vitallium® rods from the Stryker Spine RADIUS®; MANTIS® and MANTIS® Redux Spinal Systems are intended to be used with the other components of the ES2™ Spinal System.

ES2® Augmentable Spinal System

When used without cement, the ES2® Augmentable Spinal System is intended for posterior, non-cervical fixation 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, tumor and/or trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), pseudarthrosis, and/or failed previous fusion.

510(k) Summary

When used in conjunction with the Vertaplex® HV High Viscosity Radiopaque Bone Cement, the ES2® Augmentable Spinal System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. ES2® Augmentable Spinal System augmented with the Vertaplex® HV High Viscosity Radiopaque Bone Cement is for use at spinal levels where the structural integrity of the spine is not severely compromised.

Oasys® Occipito-Cervico-Thoracic System

The Stryker Spine OASYS® System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (Tl-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The Stryker Spine OASYS® System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.
The Stryker Spine OASYS® System can be linked to the Xia® System, SR90D System and Xia® 4.5 Spinal System via the rod-to-rod connectors and transition rods.

The Stryker Spine OASYS® System can also be linked to the polyaxial screws of the Xia® II and Xia® 3 Systems via the saddle connector.

Nile® Proximal Fixation Spinal Systems

The NILE Proximal Fixation Spinal System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.
The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

510(k) Summary	
	The NILE Proximal Fixation Spinal System may also be used in conjunction with other medical implants made of similar metals whenever 'wiring' may help secure the attachment of other implants. **Nile® Alternative Fixation Spinal System** The NILE Alternative Fixation System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications: 1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques; 2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis; 3. Spinal degenerative surgery, as an adjunct to spinal fusions. The NILE Alternative Fixation System may also be used in conjunction with other medical implants made of similar metals whenever 'wiring' may help secure the attachment of other implants. **Escalate™ Laminoplasty System** The Escalate™ Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The system is intended to hold the lamina open following a laminoplasty procedure.
Summary of the Technological Characteristics	The subject devices possess the same technological characteristics as the predicate devices. No changes have been made as part of this submission. The fundamental scientific technology of the subject devices remains unchanged.
Summary of the Performance Data	MR Compatibility testing per ASTM F2503 was performed. The test results demonstrate that the subject devices performance met the prescribed acceptance criteria and are substantially equivalent to the predicate devices.
Conclusion	The subject devices possess the same intended use and technological characteristics as the predicate devices and are therefore substantially equivalent.