November 7, 2024

Stryker Spine
Isabel Garza
Staff Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K242361
Trade/Device Name: OZARK Cervical Plate System; PYRENEES® Cervical Plate System; EVEREST® Spinal System; MESA® Spinal System; MESA® Small Stature Spinal System; CASPIAN® Spinal System; DENALI® Spinal System; DENALI® MI Spinal System; YUKON OCT Spinal System; Xia® 3 Spinal System; K2M Patient Specific; CASCADIA™ Interbody System; CAYMAN® Plate System; CAYMAN® Plate System-MI
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ, NKB, KWP, NKG, MAX, OVD, ODP
Dated: August 8, 2024
Received: August 9, 2024

Dear Isabel Garza:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ethan R. Naylor -S

for Ronald P. Jean, Ph.D.
Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242361

Device Name

OZARK Cervical Plate System;
PYRENEES® Cervical Plate System;
EVEREST® Spinal System;
MESA® Spinal System;
MESA® Small Stature Spinal System;
CASPIAN® Spinal System;
DENALI® Spinal System;
DENALI® MI Spinal System;
YUKON OCT Spinal System;
Xia® 3 Spinal System;
K2M Patient Specific;
CASCADIA™ Interbody System ;
CAYMAN® Plate System ;
CAYMAN® Plate System-MI

Indications for Use *(Describe)*

OZARK Cervical Plate System
OZARK Cervical Plate System is indicated for use in anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylisthesis, trauma(including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusion (Pseudarthrosis) and deformity (defined as scoliosis, kyphosis or lordosis).
PYRENEES® Cervical Plate System
PYRENEES and BLUE RIDGE Cervical Plate System are indicated for use in anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusions (pseudarthrosis) and deformity (defined as scoliosis, kyphosis or lordosis).

EVEREST® Spinal System
The EVEREST Spinal System may be used in conjunction with the RANGE® (MESA® and DENALI®) Spinal Systems, all of which are cleared for the following indications:
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; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor, pseudoarthrosis; and/or failed previous fusion.
Except for hooks, when used as an anterolateral thoracic/lumbar system the EVEREST Spinal System may also be used for the same indications as an adjunct to fusion.
When used for posterior non-cervical pedicle screw fixation in pediatric patients the EVEREST Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

MESA® Spinal System [RANGE (MESA and DENALI) Spinal System]
RANGE (MESA and DENALI) and ARI are cleared for the following indications:
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; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor, pseudoarthrosis; and/or failed previous fusion.
Except for hooks, when used as an anterolateral thoracic/lumbar system the Range Spinal System may also be used for the same indications as an adjunct to fusion.
Except for the ARI staples, the Range Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior noncervical fixation in pediatric patients. The Range Spinal System for pediatric use is intended to be used with autograft and/or allograft.
Pediatric pedicle screw fixation is limited to a posterior approach.

MESA® Small Stature Spinal System [CASPIAN OCT (MESA Mini and DENALI Mini) Spinal System]
The Caspian OCT/MESA Mini/DENALI Mini Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical 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 Caspian OCT/MESA Mini/DENALI Mini Spinal 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.
In order to achieve additional levels of fixation, the Caspian OCT/MESA Mini/DENALI Mini Spinal System may be connected to Range/MESA/DENALI Spinal System and Everest Spinal System components via the rod to rod connectors or transition rods.

CASPIAN® Spinal System [CASPIAN OCT (MESA Mini and DENALI Mini) Spinal System]
The Caspian OCT/MESA Mini/DENALI Mini Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical 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 Caspian OCT/MESA Mini/DENALI Mini Spinal 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.
In order to achieve additional levels of fixation, the Caspian OCT/MESA Mini/DENALI Mini Spinal System may be connected to Range/MESA/DENALI Spinal System and Everest Spinal System components via the rod to rod connectors or transition rods.

DENALI® Spinal System [RANGE (MESA and DENALI) Spinal System]
RANGE (MESA and DENALI) and ARI are cleared for the following indications:
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; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor, pseudoarthrosis; and/or failed previous fusion.
Except for hooks, when used as an anterolateral thoracic/lumbar system the Range Spinal System may also be used for the same indications as an adjunct to fusion.
Except for the ARI staples, the Range Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior noncervical fixation in pediatric patients. The Range Spinal System for pediatric use is intended to be used with autograft and/or allograft.
Pediatric pedicle screw fixation is limited to a posterior approach.

DENALI® MI Spinal System [CASPIAN OCT (MESA Mini and DENALI Mini) Spinal System]
The Caspian OCT/MESA Mini/DENALI Mini Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical 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 Caspian OCT/MESA Mini/DENALI Mini Spinal 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.
In order to achieve additional levels of fixation, the Caspian OCT/MESA Mini/DENALI Mini Spinal System may be connected to Range/MESA/DENALI Spinal System and Everest Spinal System components via the rod to rod connectors or transition rods.

YUKON OCT Spinal System
The YUKON OCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical 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 YUKON OCT Spinal 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.
In order to achieve additional levels of fixation, the YUKON OCT Spinal System may be connected to Everest Spinal System components via the rod to rod connectors or transition rods.

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. Pediatric pedicle screw fixation is limited to a posterior approach.

K2M Patient Specific
The EVEREST Spinal System may be used in conjunction with the RANGE® (MESA® and DENALI®) Spinal Systems, all of which are cleared for the following indications:
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; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.
Except for hooks, when used as an anterolateral thoracic/lumbar system the EVEREST Spinal System may also be used for the same indications as an adjunct to fusion.
When used for posterior non-cervical pedicle screw fixation in pediatric patients the EVEREST Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

CASCADIA™ Interbody System (CAYMAN United Plates)
The CASCADIA lumbar implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the CASCADIA lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. CASCADIA lumbar implants are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.
The CASCADIA hyperlordotic lateral lumbar implants (≥ 22°), are intended for levels L2-L5 and are to be used with CAYMAN United plates in addition to posterior supplemental fixation. The CASCADIA non-hyperlordotic lateral lumbar implants may optionally be used with CAYMAN United

plates, in addition to supplemental spinal fixation systems.
The CASCADIA cervical implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with cervical disc disease (DDD) at one level or two contiguous levels from C2 to T1. These patients should be skeletally mature and have had six weeks of non-operative treatment. The CASCADIA cervical implants are also to be used with supplemental fixation; the hyperlordotic CASCADIA cervical implants (i.e., ≥ 10°) are required to be used with an anterior cervical plate as the form of supplemental fixation.

CAYMAN® Plate System (CAYMAN Thoracolumbar and Buttress Plate Systems)
The CAYMAN Buttress Plates are intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications. The CAYMAN Thoracolumbar Plates are indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine and for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures (L5-S1). The Cayman Thoracolumbar Plate System is intended to provide temporary stabilization during fusion using autograph or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities and deformities: a) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), b) pseudoarthrosis, c) spondylolysis, d) spondylolisthesis, e) fracture, f) neoplastic disease, g) unsuccessful previous fusion surgery, h)lordotic deformities of the spine, i) thoracolumbar or lumbar scoliosis, j) deformity (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy.

CAYMAN® Plate System-MI (CAYMAN Thoracolumbar and Buttress Plate Systems)
The CAYMAN Buttress Plates are intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications. The CAYMAN Thoracolumbar Plates are indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine and for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures (L5-S1). The Cayman Thoracolumbar Plate System is intended to provide temporary stabilization during fusion using autograph or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities and deformities: a) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), b) pseudoarthrosis, c) spondylolysis, d) spondylolisthesis, e) fracture, f) neoplastic disease, g) unsuccessful previous fusion surgery, h)lordotic deformities of the spine, i) thoracolumbar or lumbar scoliosis, j) deformity (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy.

CAYMAN® Plate System (CAYMAN LP Plate System)
The CAYMAN LP Plate System is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

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.

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510(k) Summary: Stryker Spine Plate and Screw Systems

Submitter:	Stryker Spine, K2M Inc. 600 Hope Parkway SE Leesburg, Virginia 20175
Contact Person :	Name: Isabel Garza Phone: 201-749-8610 Email: isabel.garza@stryker.com Secondary Contact: Name: Shraddha Moore Phone: 201-831-5804 Email: shraddha.more@stryker.com
Date Prepared:	November 7, 2024
Trade Names:	1. OZARK Cervical Plate System 2. PYRENEES® Cervical Plate System 3. EVEREST® Spinal System 4. MESA® Spinal System 5. MESA® Small Stature Spinal System 6. CASPIAN® Spinal System 7. DENALI® Spinal System 8. DENALI® MI Spinal System 9. YUKON OCT Spinal System 10. Xia® 3 Spinal System 11. K2M Patient Specific 12. CASCADIA™ Interbody System (Cayman Unites Plates) 13. CAYMAN® Plate System 14. CAYMAN® Plate System-MI
Common Name:	Spinal Fixation System
Classification:	Class II
Product Code and Classification Name:	1. OZARK Cervical Plate System **KWQ –** Spinal intervertebral body fixation orthosis (21 CFR Part §888.3060) 2. PYRENEES® Cervical Plate System **KWQ –** Spinal intervertebral body fixation orthosis (21 CFR Part §888.3060) 3. EVEREST® Spinal System **NKB –** Thoracolumbosacral pedicle screw system (21 CFR Part §888.3070)

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510(k) Summary: Stryker Spine Plate and Screw Systems

	KWP – Spinal interlaminal fixation orthosis (21 CFR Part §888.3050) **KWQ –** Spinal intervertebral body fixation orthosis (21 CFR Part §888.3060) 4. MESA® Spinal System **NKB –** Thoracolumbosacral pedicle screw system (21 CFR Part §888.3070) **KWP –** Spinal interlaminal fixation orthosis (21 CFR Part §888.3050) **KWQ –** Spinal intervertebral body fixation orthosis (21 CFR Part §888.3060) 5. MESA® Small Stature Spinal System **NKG –** Orthosis, cervical pedicle screw spinal fixation (Unclassified) **KWP –** Spinal interlaminal fixation orthosis (21 CFR Part §888.3050) 6. CASPIAN® Spinal System **NKG –** Orthosis, cervical pedicle screw spinal fixation (Unclassified) **KWP –** Spinal interlaminal fixation orthosis (21 CFR Part §888.3050) 7. DENALI® Spinal System **NKB –** Thoracolumbosacral pedicle screw system (21 CFR Part §888.3070) **KWP –** Spinal interlaminal fixation orthosis (21 CFR Part §888.3050) **KWQ –** Spinal intervertebral body fixation orthosis (21 CFR Part §888.3060) 8. DENALI® MI Spinal System **NKG –** Orthosis, cervical pedicle screw spinal fixation (Unclassified) **KWP –** Spinal interlaminal fixation orthosis (21 CFR Part §888.3050) 9. YUKON OCT Spinal System **NKG –** Orthosis, cervical pedicle screw spinal fixation (Unclassified) **KWP –** Spinal interlaminal fixation orthosis (21 CFR Part §888.3050) 10. K2M Patient Specific **NKB –** Thoracolumbosacral pedicle screw system (21 CFR Part §888.3070) **KWP –** Spinal interlaminal fixation orthosis (21 CFR Part §888.3050) **KWQ –** Spinal intervertebral body fixation orthosis (21 CFR Part §888.3060) 11. Xia® 3 Spinal System **NKB –** Thoracolumbosacral pedicle screw system (21 CFR Part §888.3070) **KWP –** Spinal interlaminal fixation orthosis (21 CFR Part §888.3050) **KWQ –** Spinal intervertebral body fixation orthosis (21 CFR Part §888.3060)

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510(k) Summary: Stryker Spine Plate and Screw Systems

	12. CASCADIA™ Interbody System (CAYMAN United Plates) **ODP –** Intervertebral fusion Device with Bone Graft, Cervical (21 CFR Part §888.3080) **MAX –** Intervertebral fusion Device with Bone Graft, lumbar (21 CFR Part §888.3080) **OVD –** Intervertebral fusion Device with Integrated Fixation, lumbar (21 CFR Part §888.3080) 13. CAYMAN® Plate System **KWQ –** Spinal intervertebral body fixation orthosis (21 CFR Part §888.3060) 14. CAYMAN® Plate System-MI **KWQ –** Spinal intervertebral body fixation orthosis (21 CFR Part §888.3060)
Predicate Devices:	**Primary Predicate:** • PYRENEES Cervical Plate System, BLUE RIDGE Cervical Plate System, OZARK Cervical Plate System, CAYMAN Thoracolumbar and Buttress Plate Systems *(K182473)* **Additional Predicates:** • EVEREST Spinal System, RANGE (MESA and DENALI) Spinal System, CASPIAN OCT (MESA Mini and DENALI Mini) Spinal System, YUKON OCT Spinal System *(K181603)* • K2M Patient Specific Rods *(K180376)* • 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, Escalate® Laminoplasty System *(K222684)* • CAYMAN LP Plate System *(K190584)* • CASCADIA Interbody System (CAYMAN United plates) *(K172941)* • EVEREST Spinal System *(K173508)* • EVEREST Spinal System *(K161369)* • Pyrenees Cervical Plate System *(K153526)*

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510(k) Summary: Stryker Spine Plate and Screw Systems	
	• Nile Alternative Fixation *(K143350)* • Range/Mesa/Denali Spinal System *(K141873)* • Range/Mesa/Denali Spinal System *(K140765)* • Range Spinal System, Everest Spinal System *(K133944)* • Cayman Plate System *(K131533)* • XIA® 3 Spinal System *(K113666)* • Xia® 3 and Xia® 4.5 Spinal Systems *(K142381)* • Range Spinal System *(K070229)* • Ozark™ Cervical Plate System *(K172104)* • Everest Spinal System *(K151727)* • Range/Denali/Mesa Spinal System *(K143334)* • Everest Spinal System *(K103440)* • Cayman Thoracolumbar Plate System *(K081380)* • Range Spinal System *(K112920)*
Device Description:	The previously cleared devices consist of a variety of plate and screw systems designed to provide support across implanted levels in the cervical, thoracolumbar, and lumbosacral spine until fusion is achieved. The primary purpose of this submission is to update previously cleared MR safety information, establish an MR Conditional labeling claim, update cleaning, disinfection and sterilization instructions.
Intended Use/Indication for Use:	**OZARK Cervical Plate System** OZARK Cervical Plate System is indicated for use in anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylisthesis, trauma(including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusion (Pseudarthrosis) and deformity (defined as scoliosis, kyphosis or lordosis). **PYRENEES® Cervical Plate System** PYRENEES and BLUE RIDGE Cervical Plate System are indicated for use in anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusions (pseudarthrosis) and deformity (defined as scoliosis, kyphosis or lordosis).

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	EVEREST® Spinal System The EVEREST Spinal System may be used in conjunction with the RANGE® (MESA® and DENALI®) Spinal Systems, all of which are cleared for the following indications: 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; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor, pseudoarthrosis; and/or failed previous fusion. Except for hooks, when used as an anterolateral thoracic/lumbar system the EVEREST Spinal System may also be used for the same indications as an adjunct to fusion. When used for posterior non-cervical pedicle screw fixation in pediatric patients the EVEREST Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. **MESA® Spinal System *[RANGE (MESA and DENALI) Spinal System]*** RANGE (MESA and DENALI) and ARI are cleared for the following indications: 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; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor, pseudoarthrosis; and/or failed previous fusion. Except for hooks, when used as an anterolateral thoracic/lumbar system the Range Spinal System may also be used for the same indications as an adjunct to fusion. Except for the ARI staples, the Range Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior noncervical fixation in pediatric patients. The Range Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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	MESA® Small Stature Spinal System ***[CASPIAN OCT (MESA Mini and DENALI Mini) Spinal System]*** The Caspian OCT/MESA Mini/DENALI Mini Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical 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 Caspian OCT/MESA Mini/DENALI Mini Spinal 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. In order to achieve additional levels of fixation, the Caspian OCT/MESA Mini/DENALI Mini Spinal System may be connected to Range/MESA/DENALI Spinal System and Everest Spinal System components via the rod to rod connectors or transition rods. **CASPIAN® Spinal System** ***[CASPIAN OCT (MESA Mini and DENALI Mini) Spinal System]*** The Caspian OCT/MESA Mini/DENALI Mini Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical 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 Caspian OCT/MESA Mini/DENALI Mini Spinal 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.

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In order to achieve additional levels of fixation, the Caspian OCT/MESA Mini/DENALI Mini Spinal System may be connected to Range/MESA/DENALI Spinal System and Everest Spinal System components via the rod to rod connectors or transition rods.

DENALI® Spinal *System [RANGE (MESA and DENALI) Spinal System]*
RANGE (MESA and DENALI) and ARI are cleared for the following indications:

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; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor, pseudoarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system the Range Spinal System may also be used for the same indications as an adjunct to fusion.

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

DENALI® MI Spinal System *[CASPIAN OCT (MESA Mini and DENALI Mini) Spinal System]*
The Caspian OCT/MESA Mini/DENALI Mini Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical 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 Caspian OCT/MESA Mini/DENALI Mini Spinal 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

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	cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the Caspian OCT/MESA Mini/DENALI Mini Spinal System may be connected to Range/MESA/DENALI Spinal System and Everest Spinal System components via the rod to rod connectors or transition rods. **YUKON OCT Spinal System** The YUKON OCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical 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 YUKON OCT Spinal 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. In order to achieve additional levels of fixation, the YUKON OCT Spinal System may be connected to Everest Spinal System components via the rod to rod connectors or transition rods. **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)

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- 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.

K2M Patient Specific
The EVEREST Spinal System may be used in conjunction with the RANGE® (MESA® and DENALI®) Spinal Systems, all of which are cleared for the following indications:

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; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system the EVEREST Spinal System may also be used for the same indications as an adjunct to fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients the EVEREST Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior

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approach.

CASCADIA™ Interbody System *(CAYMAN United Plates)*
The CASCADIA lumbar implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the CASCADIA lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. CASCADIA lumbar implants are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

The CASCADIA hyperlordotic lateral lumbar implants (≥ 22°), are intended for levels L2-L5 and are to be used with CAYMAN United plates in addition to posterior supplemental fixation. The CASCADIA non-hyperlordotic lateral lumbar implants may optionally be used with CAYMAN United plates, in addition to supplemental spinal fixation systems.

The CASCADIA cervical implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with cervical disc disease (DDD) at one level or two contiguous levels from C2 to T1. These patients should be skeletally mature and have had six weeks of non-operative treatment. The CASCADIA cervical implants are also to be used with supplemental fixation; the hyperlordotic CASCADIA cervical implants (i.e., ≥ 10°) are required to be used with an anterior cervical plate as the form of supplemental fixation.

CAYMAN® Plate System *(CAYMAN Thoracolumbar and Buttress Plate Systems)*
The CAYMAN Buttress Plates are intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications. The CAYMAN Thoracolumbar Plates are indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar

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	(T1-L5) spine and for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures (L5-S1). The Cayman Thoracolumbar Plate System is intended to provide temporary stabilization during fusion using autograph or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities and deformities: a) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), b) pseudoarthrosis, c) spondylolysis, d) spondylolisthesis, e) fracture, f) neoplastic disease, g) unsuccessful previous fusion surgery, h)lordotic deformities of the spine, i) thoracolumbar or lumbar scoliosis, j) deformity (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy. **CAYMAN® Plate System-MI *(CAYMAN Thoracolumbar and Buttress Plate Systems)*** The CAYMAN Buttress Plates are intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications. The CAYMAN Thoracolumbar Plates are indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine and for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures (L5-S1). The Cayman Thoracolumbar Plate System is intended to provide temporary stabilization during fusion using autograph or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities and deformities: a) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), b) pseudoarthrosis, c) spondylolysis, d) spondylolisthesis, e) fracture, f) neoplastic disease, g) unsuccessful previous fusion surgery, h)lordotic deformities of the spine, i) thoracolumbar or lumbar scoliosis, j) deformity (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy. **CAYMAN® Plate System *(CAYMAN LP Plate System)*** The CAYMAN LP Plate System is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

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Summary of the Technological Characteristics:	The devices in this submission possess similar technological characteristics as their predicate devices. Changes implemented since the last clearance of the subject devices were assessed and detailed in this submission. Minor differences in technological characteristics of the subject devices do not impact safety and efficacy of the devices. Therefore, the fundamental scientific technology of the subject devices is the same as previously cleared devices.
Summary of the Performance Data:	MR Compatibility testing (MR Image Artifacts, Magnetically Induced Torque, Magnetically Induced Displacement Force, RF-Induced Heating) per ASTM F2503-23e1 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/indications for use and similar technological characteristics as the predicate devices. Per the assessments detailed in this submission, minor differences in technological characteristics of the subject devices and updates to the labeling do not impact safety and efficacy of the devices. Therefore, the subject devices are substantially equivalent to their predicate devices.