February 14, 2023

Stryker Spine
Ms. Renée Norby
Staff Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K221490

Trade/Device Name: Tritanium® C Anterior Cervical Cage, Tritanium® PL Cage, Tritanium® TL Curved Posterior Lumbar Cage, Tritanium® X PL Expandable Posterior Lumbar Cage, Tritanium® X TL Expandable Curved Posterior Lumbar Cage, Stryker Spine VLIFT™ Vertebral Body Replacement System, VLIFT®-s Vertebral Body Replacement System, Ascential IBD PEEKc Spacer, Aero™-AL Lumbar Cage System, Aero™-LL Lumbar Cage System, Aero®-C Cervical Cage System, AVS® Aria PEEK Spacer, AVS® Anchor-C Cervical Cage System, AVS® Anchor-L Spacer, AVS® TL PEEK Spacer, AVS® PL PEEK Spacer, AVS® AL PEEK Spacer, AVS® UniLIF PEEK Spacer, AVS® Navigator PEEK Spacer, AVS® AS PEEK Spacer, Monterey™ AL Interbody System, Aleutian IBF System, Capri Corpectomy Cage System, Cascadia Interbody System, Chesapeake Stabilization System, Mojave Expandable Interbody System, Sahara Stabilization System, Santorini Corpectomy Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX, OVD, MQP, PLR
Dated: January 13, 2023
Received: January 13, 2023

Dear Ms. Norby:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221490

Device Name
Aero™-AL Lumbar Cage System

Indications for Use *(Describe)*
The Stryker Spine Aero™ -AL is an intervertebral body fusion device indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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 degeration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The Aero™ - AL Lumbar Cage System is to be implanted via an anterior approach.

The Aero™ - AL Lumbar Cage System is intended to be used with supplemental spinal fixation systems that hae been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems) in addition to the included fixation anchors.

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

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

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510(k) Number *(if known)*

K221490

Device Name
Aero®-C Cervical Cage System

Indications for Use *(Describe)*

The Stryker Spine AERO®-C Cervical Cage is indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-Tl disc.

DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have six weeks of non-operative therapy.

The AERO®-C Cervical Cage System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach.

The AERO®-C Cervical Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine. In addition, the device must be used with the included fixation anchors.

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

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

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510(k) Number *(if known)*

K221490

Device Name

Aero™-LL Lumbar Cage System

Indications for Use *(Describe)*

The Stryker Spine Aero™ -LL is an intervertebral body fusion device indicated for use with autogenous bone graft 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 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The Aero™ -LL Lumbar Cage System is to be implanted via a lateral approach.

The Aero™ -LL Lumbar Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems). In addition, the device may be used with or without the included fixation anchors.

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

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

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510(k) Number *(if known)*
K221490

Device Name
Aleutian IBF System

Indications for Use *(Describe)*
When used as a cervical intervertebral body fusion device, the Aleutian implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to Tl, for the treatment of cervical disc disease (defined as neck pain of disco genie origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the Aleutian implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S 1, for the treatment of degenerative disc disease (DOD) with up to Grade I spondylolisthesis. ODD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

When used as vertebral body replacement devices the Aleutian implants are indicated for use in the thoracolumbar spine (Tl to LS) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body, resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aleutian implants are designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

For all the above indications the Aleutian implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate 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)

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510(k) Number *(if known)*

K221490

Device Name

Ascential IBD PEEKc Spacer

Indications for Use *(Describe)*

The Ascential IBD PEEKc Spacers are indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Ascential IBD PEEKc Spacers are to be used with autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and are to be implanted via an open, anterior approach.

The Ascential IBD PEEKc Spacer is intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

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

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

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510(k) Number *(if known)*

K221490

Device Name
AVS® AL PEEK Spacer

Indications for Use *(Describe)*

The Stryker Spine AVS® AL and AVS® ALign PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used an adjunct to fusion in patients with degenerative disc disease (DDD) and 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 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the AVS® AL and AVS® ALign PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® AL and AVS® ALign PEEK Spacers are to be implanted via anterior or anterolateral approach.

The AVS® AL and AVS® ALign PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine.

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

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

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See PRA Statement below.

510(k) Number *(if known)*

K221490

Device Name
AVS® Anchor-C Cervical Cage System

Indications for Use *(Describe)*

The Stryker Spine AVS® Anchor-C Cervical Cage System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The AVS® Anchor-C Cervical Cage is to be used with autogenous bone graft and implanted via an open, anterior approach.

The AVS® Anchor-C Cervical Cage must be used with the internal screw fixation provided by AVS® Anchor-C Fixation Screws. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

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

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

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510(k) Number *(if known)*
K221490

Device Name
AVS® Anchor-L Spacer

Indications for Use *(Describe)*
The Stryker Spine AVS® Anchor-L is an intervertebral body fusion device indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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 degeration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The AVS® Anchor-L Lumbar Cage system is to be implanted via an open, anterior approach.

The AVS® Anchor-L Lumbar Cage system may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the AVS® Anchor-L Lumbar Cage must be used with the internal screw and plate fixation provided by the AVS® Anchor-L Fixation Screws and Locking Plate. If AVS® Anchor-L is used with less than three or none of the provided screws, then additional supplemental fixation that has been cleared by the FDA for use in the lumbar spine must be used to augment stability. The accompanying Locking Plate must be used anytime the device is used with any number of screws.

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

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

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Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221490

Device Name
AVS® Aria PEEK Spacer

Indications for Use *(Describe)*
The Stryker Spine AVS® ARIA PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the AVS® ARIA PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® ARIA PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine.

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

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

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510(k) Number *(if known)*
K221490

Device Name
AVS® AS PEEK Spacer

Indications for Use *(Describe)*
The Stryker Spine AVS® AS PEEK Spacers are indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AVS® AS PEEK Spacers are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and are to be implanted via an open, anterior approach.

The AVS® AS PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

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

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

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510(k) Number *(if known)*

K221490

Device Name
AVS® Navigator PEEK Spacer

Indications for Use *(Describe)*

The Stryker Spine AVS® Navigator PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the AVS® Navigator PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® Navigator PEEK Spacers are to be implanted via a posterior or posterolateral approach.

The AVS® Navigator PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine.

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

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

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510(k) Number *(if known)*

K221490

Device Name
AVS® PL PEEK Spacer

Indications for Use *(Describe)*

The Stryker Spine AVS® PL and AVS® UniLIF™ PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the AVS® PL and AVS® UniLIF™ PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® PL PEEK Spacers and AVS® UniLIF™ PEEK Spacers are to be implanted via posterior approach.

The AVS® PL PEEK Spacers and AVS® UniLIF™ PEEK Spacers are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod 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)

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510(k) Number *(if known)*

K221490

Device Name

AVS® TL PEEK Spacer

Indications for Use *(Describe)*

The Stryker Spine AVS® TL PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used an adjunct to fusion in patients with degenerative disc disease (DDD) and 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 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the AVS® TL PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® TL PEEK Spacers are to be implanted via posterior approach.

The AVS® TL PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod 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)

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510(k) Number *(if known)*

K221490

Device Name
AVS® UniLIF PEEK Spacer

Indications for Use *(Describe)*

The Stryker Spine AVS® PL and AVS® UniLIF™ PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the AVS® PL and AVS® UniLIF™ PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® PL PEEK Spacers and AVS® UniLIF™ PEEK Spacers are to be implanted via posterior approach.

The AVS® PL PEEK Spacers and AVS® UniLIF™ PEEK Spacers are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod 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)

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510(k) Number *(if known)*

K221490

Device Name
Capri Corpectomy Cage System

Indications for Use *(Describe)*

CAPRI Corpectomy Cages are vertebral body replacement devices intended for use in the cervical and thoracolumbar spine.

When used in the cervical spine (C2-T1), CAPRI Static and Expandable cages are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These cages are intended to restore 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, with bone graft used at the surgeon's discretion.

When used in the thoracolumbar spine (T1-L5), CAPRI Static and Expandable cages are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor and trauma (i.e. fracture). These are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

The interior of the cages can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion.

When used in the thoracolumbar spine, the CAPRI Static and Expandable Corpectomy cages are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

When used in the cervical spine at one or two levels, the CAPRI Static and Expandable cages are intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation which is cleared by the FDA.

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

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

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510(k) Number *(if known)*
K221490

Device Name
Cascadia Interbody System

Indications for Use *(Describe)*
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.

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

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

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510(k) Number *(if known)*

K221490

Device Name
Chesapeake Stabilization System

Indications for Use *(Describe)*

When used as a cervical intervertebral body fusion device, the CHESAPEAKE Stabilization System implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the CHESAPEAKE Stabilization System implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The Lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

The hyperlordotic lumbar implants (i.e., > 15°) must be used with supplemental fixation (i.e., posterior pedicle screw and rod system) cleared for use in the lumbar spine, in addition to the bone screws provided. Otherwise, the Chesapeake Stabilization System implants (i.e., ≤15°) may be used as a stand-alone device, which is intended to be used with the bone screws provided (i.e., 2 or 3 screws for the 2-screw and 3-screw implants, respectively).

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

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510(k) Number *(if known)*

K221490

Device Name

Mojave Expandable Interbody System

Indications for Use *(Describe)*

The MOJAVE Expandable Interbody System 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 (DOD) 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 MOJAVE lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. MOJAVE lumbar implants are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

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

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

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510(k) Number *(if known)*

K221490

Device Name
Monterey AL Interbody System

Indications for Use *(Describe)*

Monterey™ AL Interbody System – Stand-Alone
The Stryker Spine Monterey™ AL Interbody System – Stand-Alone (AL Stand-Alone) is an interbody fusion device 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 or two contiguous levels from L2-S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These 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 non-operative therapy.

Additionally, the Monterey™ AL Stand-Alone System can be used as adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Monterey™ AL Stand-Alone System is intended to be implanted via an anterior approach.

The Monterey™ AL Stand-Alone System may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Monterey™ AL Stand-Alone System must be used with the bone screws provided and requires no additional supplemental fixation. If Monterey™ AL Stand-Alone System is used with less than three or none of the provided bone screws, then additional supplemental fixation that has been cleared by the FDA for use in the lumbosacral spine must be used to augment stability. Hyperlordotic implants (>20° lordosis) are intended to be used with supplemental fixation (e.g., posterior fixation).

Monterey™ AL Interbody System – Spacer
The Stryker Spine Monterey™ AL Interbody System – Spacer (AL Spacer) is an intervertebral body fusion device 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 or two contiguous levels from L2-S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These 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 non-operative therapy.

Additionally, the Monterey™ AL Spacer System can be used as adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Monterey™ AL Spacer System is intended to be implanted via an anterior approach.

The Monterey™ AL Spacer System is intended to be used with supplemental fixation systems that have been cleared by the FDA for use in the lumbosacral spine.

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

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

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510(k) Number *(if known)*
K221490

Device Name
Sahara Stabilization System

Indications for Use *(Describe)*
The SAHARA Stabilization System 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 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the SAHARA implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

Hyperlordotic (angles > 15°) and Lateral implants must be used with supplemental fixation (i.e., posterior pedicle screw and rod system) cleared for use in the lumbar spine, in addition to the bone screws provided. Additional supplemental fixation (i.e. pedicle screw and rod system) is needed when used as an adjunct to fusion for degenerative scoliosis. Otherwise, the SAHARA Stabilization System implants may be used as a stand-alone device, which is intended to be used with the bone screws provided.

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

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

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510(k) Number *(if known)*

K221490

Device Name
Santorini Corpectomy Cage System

Indications for Use *(Describe)*

SANTORINI Corpectomy Cages are vertebral body replacement devices intended for use in the cervical and thoracolumbar spine.

When used in the cervical spine (C2-T1), SANTORINI cages are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These cages are intended to restore 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, with bone graft used at the surgeon's discretion.

When used in the thoracolumbar spine (T1-L5), SANTORINI cages are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor and trauma (i.e. fracture). These cages are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

The interior of the cages can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion.

When used in the thoracolumbar spine, the Santorini Corpectomy cages are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

When used in the cervical spine at one or two levels, the SANTORINI Corpectomy Cage System is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation which is cleared by the FDA.

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

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

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510(k) Number *(if known)*
K221490

Device Name
Tritanium® C Anterior Cervical Cage

Indications for Use *(Describe)*
The Tritanium® C Anterior Cervical Cage is indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels from the C2 to T1 disc.

DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have six weeks of non-operative therapy.

The Tritanium® C Anterior Cervical Cage System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach.

The Tritanium® C Anterior Cervical Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine.

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

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

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510(k) Number *(if known)*

K221490

Device Name
Tritanium® PL Cage

Indications for Use *(Describe)*

The Stryker Spine Tritanium® PL Cage is an intervertebral body fusion device 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 at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the Tritanium® PL Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Tritanium® PL Cage is to be implanted via a posterior approach.

The Tritanium® PL Cage is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

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

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

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510(k) Number *(if known)*
K221490

Device Name
Tritanium® TL Curved Posterior Lumbar Cage

Indications for Use *(Describe)*
The Stryker Spine Tritanium® TL cage is an intervertebral body fusion device 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 at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the Tritanium TL Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Tritanium TL Cage is to be implanted via a posterior approach.

The Tritanium TL Cage is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

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

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

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510(k) Number *(if known)*

K221490

Device Name

Tritanium® X PL Expandable Posterior Lumbar Cage

Indications for Use *(Describe)*

The Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are intended for intervertebral body fusion with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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. These 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 completed six months of non-operative treatment.

Additionally, the Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are always to be used with supplemental internal spinal fixation. Additionally, the Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion.

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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221490

Device Name
Tritanium® X TL Expandable Curved Posterior Lumbar Cage

Indications for Use *(Describe)*
The Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are intended for intervertebral body fusion with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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. These 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 completed six months of non-operative treatment.

Additionally, the Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are always to be used with supplemental internal spinal fixation. Additionally, the Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion.

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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K221490

Device Name
Stryker Spine VLIFT™ Vertebral Body Replacement System

Indications for Use *(Describe)*

Stryker Spine VLIFT™ is a vertebral body replacement system intended to replace a vertebral body or an entire vertebra. It is for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body or vertebra resected or excised during total and partial corpectomy and vertebrectomy procedures due to tumor or trauma (i.e., fracture). For both corpectomy and vertebrectomy procedures, the VLIFT™ system is intended to be used with supplemental internal fixation systems. The supplemental internal fixation systems that may be used with VLIFT™ include, but are not limited to Stryker Spine plate or rod systems (Xia® Spinal System, Spiral Radius 90D, and Trio). The use of bone graft with VLIFT™ is optional.

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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221490

Device Name
VLIFT®-s Vertebral Body Replacement System

Indications for Use *(Describe)*
VLIFT®-s Vertebral Body Replacement System is indicated for use in the cervical spine (C3-C7) and the thoracolumbar spine (T1-L5) in skeletally mature patients for partial or total replacement of a diseased, collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e., fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissue in degenerative disorders.

The VLIFT®-s Vertebral Body Replacement System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The VLIFT®-s Vertebral Body Replacement 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, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The VLIFT®-s Vertebral Body Replacement System is intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.

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

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

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stryker

510(k) Summary	
Submitter:	Stryker Spine 600 Hope Pkwy SE Leesburg, VA 20175
Contact Person :	Name: Renee Norby Phone: 201-725-4954 Email: renee.norby@stryker.com
Date Prepared:	19-May-2022
Trade Names:	1. Tritanium® C Anterior Cervical Cage 2. Tritanium® PL Cage 3. Tritanium® TL Curved Posterior Lumbar Cage 4. Tritanium® X PL Expandable Posterior Lumbar Cage 5. Tritanium® X TL Expandable Curved Posterior Lumbar Cage 6. Stryker Spine VLIFT™ Vertebral Body Replacement System 7. VLIFT®-s Vertebral Body Replacement System 8. Ascential IBD PEEKc Spacer 9. Aero™-AL Lumbar Cage System 10. Aero™-LL Lumbar Cage System 11. Aero®-C Cervical Cage System 12. AVS® Aria PEEK Spacer 13. AVS® Anchor-C Cervical Cage System 14. AVS® Anchor-L Spacer 15. AVS® TL PEEK Spacer/AVS® TL PEEK Spacer Sterile 16. AVS® PL PEEK Spacer 17. AVS® AL/AVS® AL Sterile PEEK Spacer 18. AVS® UniLIF PEEK Spacer 19. AVS® Navigator PEEK Spacer 20. AVS® AS PEEK Spacer 21. Monterey™ AL Interbody System 22. Aleutian IBF System 23. Capri Corpectomy Cage System 24. Cascadia Interbody System 25. Chesapeake Stabilization System 26. Mojave Expandable Interbody System 27. Sahara Stabilization System 28. Santorini Corpectomy Cage System
Common Name:	1. Tritanium® C Intervertebral body fusion device 2. Tritanium® PL Intervertebral body fusion device 3. Tritanium® TL Intervertebral body fusion device

510(k) Summary	
	4. Tritanium® X PL Intervertebral body fusion device 5. Tritanium® X TL Intervertebral body fusion device 6. VLIFT™ Spinal Vertebral Body Replacement System 7. VLIFT®-s Spinal Vertebral Body Replacement Device 8. Ascential IBD PEEKc Spacer Cervical Interbody Device 9. Aero™-AL Intervertebral fusion device with integrated fixation, lumbar 10. Aero™-LL Intervertebral fusion device with integrated fixation, lumbar 11. Aero®-C Intervertebral fusion device with bone graft, cervical 12. AVS® Aria Intervertebral fusion device with bone graft, lumbar 13. AVS® Anchor-C Intervertebral fusion device with bone graft, cervical 14. AVS® Anchor-L Intervertebral fusion device with bone graft, lumbar 15. AVS® TL/AVS® TL Sterile Intervertebral fusion device with bone graft, lumbar 16. AVS® PL Intervertebral fusion device with bone graft, lumbar 17. AVS® AL/AVS® AL Sterile Intervertebral fusion device with bone graft, lumbar 18. AVS® UniLIF Intervertebral fusion device with bone graft, lumbar 19. AVS® Nav Intervertebral fusion device with bone graft, lumbar 20. AVS® AS Intervertebral fusion device with bone graft, cervical 21. Monterey™ AL Interbody System Intervertebral body fusion device 22. Aleutian IBF System Intervertebral body fusion device 23. Capri Corpectomy Cage System Vertebral body replacement device 24. Cascadia Interbody System

510(k) Summary	
	Intervertebral fusion device 25. Chesapeake Stabilization System Spinal fixation system 26. Mojave Expandable Interbody System Intervertebral fusion device with bone graft 27. Sahara Stabilization System Spinal fixation system 28. Santorini Corpectomy Cage System Vertebral body replacement device
Proposed Class:	Class II
Classification Name:	1. Tritanium® C Intervertebral Body Fusion Device; 21 CFR §888.3080 2. Tritanium® PL Intervertebral Body Fusion Device; 21 CFR §888.3080 3. Tritanium® TL Intervertebral Body Fusion Device with Bone Graft, Lumbar; 21 CFR §888.3080 4. Tritanium® X PL Intervertebral Body Fusion Device with Bone Graft, Lumbar; 21 CFR §888.3080 5. Tritanium® X TL Intervertebral Body Fusion Device with Bone Graft, Lumbar; 21 CFR §888.3080 6. VLIFT™ Spinal Intervertebral Body Fixation Orthosis; 21 CFR §888.3060 7. VLIFT®-s Spinal Intervertebral Body Fixation Orthosis; 21 CFR §888.3060 8. Ascential IBD PEEKc Spacer Intervertebral Body Fixation Device; 21 CFR §888.3080 9. Aero™-AL Intervertebral body fusion device; 21 CFR §888.3080 10. Aero™-LL Intervertebral body fusion device; 21 CFR §888.3080 11. Aero®-C Intervertebral body fusion device; 21 CFR §888.3080 12. AVS® Aria Intervertebral body fusion device; 21 CFR §888.3080 13. AVS® Anchor-C Intervertebral body fusion device; 21 CFR §888.3080 14. AVS® Anchor-L

510(k) Summary	
	Intervertebral body fusion device; 21 CFR §888.3080 15. AVS® TL/AVS® TL Sterile Intervertebral body fusion device; 21 CFR §888.3080 16. AVS® PL Intervertebral body fusion device; 21 CFR §888.3080 17. AVS® AL/AVS® AL Sterile Intervertebral body fusion device; 21 CFR §888.3080 18. AVS® UniLIF Intervertebral body fusion device; 21 CFR §888.3080 19. AVS® Nav Intervertebral body fusion device; 21 CFR §888.3080 20. AVS® AS Intervertebral body fusion device; 21 CFR §888.3080 21. Monterey™ AL Interbody System Intervertebral body fusion device; 21 CFR §888.3080 22. Aleutian IBF System Intervertebral fusion device with bone graft, lumbar; 21 CFR §888.3080 Intervertebral fusion device with bone graft, cervical; 21 CFR §888.3080 Spinal vertebral body replacement device; 21 CFR §888.3060 23. Capri Corpectomy Cage System Spinal intervertebral body fixation orthosis; 21 CFR §888.3060 24. Cascadia Interbody System Intervertebral fusion device with bone graft, lumbar; 21 CFR §888.3080 Intervertebral fusion device with integrated fixation, lumbar; 21 CFR §888.3080 Intervertebral fusion device with bone graft, cervical; 21 CFR §888.3080 25. Chesapeake Stabilization System Intervertebral body fusion device with integrated fixation; 21 CFR §888.3080 26. Mojave Expandable Interbody System Intervertebral fusion device with bone graft, lumbar; 21 CFR §888.3080 27. Sahara Stabilization System Intervertebral fusion device with integrated fixation, lumbar; 21 CFR §888.3080 Intervertebral fusion device with bone graft, lumbar; 21 CFR §888.3080 28. Santorini Corpectomy Cage System Spinal intervertebral body fixation orthosis; 21 CFR §888.3060
Product Code:	1. Tritanium® C ODP 2. Tritanium® PL

510(k) Summary

	MAX 3. Tritanium® TL MAX 4. Tritanium® X PL MAX 5. Tritanium® X TL MAX 6. VLIFT™ MQP 7. VLIFT®-s PLR, MQP 8. Ascential IBD PEEKc Spacer ODP 9. Aero™-AL OVD 10. Aero™-LL OVD, MAX 11. Aero®-C ODP 12. AVS® Aria MAX 13. AVS® Anchor-C ODP 14. AVS® Anchor-L OVD, MAX 15. AVS® TL/AVS® TL Sterile MAX 16. AVS® PL MAX 17. AVS® AL/AVS® AL Sterile MAX 18. AVS® UniLIF MAX 19. AVS® Nav MAX 20. AVS® AS ODP 21. Monterey™ AL Interbody System OVD, MAX 22. Aleutian IBF System MAX, ODP, MQP

510(k) Summary	
	23. Capri Corpectomy Cage System PLR, MQP 24. Cascadia Interbody System MAX, OVD, ODP 25. Chesapeake Stabilization System OVD, OVE 26. Mojave Expandable Interbody System MAX 27. Sahara Stabilization System OVD, MAX 28. Santorini Corpectomy Cage System PLR, MQP
Predicate Devices:	**Primary Predicate:** Tritanium® C (K171496) **Additional Predicates:** Tritanium® PL (K181014) Tritanium® TL (K173476) Tritanium® X PL (K183249) Tritanium® X TL (K183249) VLIFT™ (K060506) VLIFT®-s (K183071) Ascential IBD PEEKc Spacer (K161407) Aero™-AL (K143163) Aero™-LL (K142066) Aero®-C (K152532) AVS® Aria (K151726) AVS® Anchor C (K102606) AVS® Anchor L (K143163) AVS® TL/AVS® TL Sterile (K151726) AVS® PL (K151726) AVS® AL/AVS® AL Sterile (K151726) AVS® UniLIF (K151726) AVS® Nav (K151726) AVS® AS (K142251) Monterey™ AL Interbody System (K201585) Aleutian IBF System (K133614) Capri Corpectomy Cage System (K211320) Cascadia Interbody System (K172941) Chesapeake Stabilization System (K142487) Mojave Expandable Interbody System (K193203) Sahara Stabilization System (K190179) Santorini Corpectomy Cage System (K180665)

510(k) Summary	
Device Description:	The subject devices consist of a variety of intervertebral body fusion devices and spinal vertebral body replacement devices designed to provide support across implanted levels of the cervical, thoracolumbar, and lumbosacral spine until fusion is achieved and have been previously cleared by FDA. The purpose of this submission is to establish an MR Conditional labeling claim for these implants.
Intended Use:	**Tritanium® C** The Tritanium® C Anterior Cervical Cage is indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels from the C2 to T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have six weeks of non-operative therapy. The Tritanium® C Anterior Cervical Cage System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach. The Tritanium® C Anterior Cervical Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine. **Tritanium® PL** The Stryker Spine Tritanium® PL Cage is an intervertebral body fusion device 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 at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the Tritanium® PL Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The Tritanium® PL Cage is to be implanted via a posterior approach. The Tritanium® PL Cage is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

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Tritanium® TL
The Stryker Spine Tritanium® TL cage is an intervertebral body fusion device 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 at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the Tritanium TL Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Tritanium TL Cage is to be implanted via a posterior approach.

The Tritanium TL Cage is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

Tritanium® X PL
The Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are intended for intervertebral body fusion with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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. These 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 completed six months of non-operative treatment.

Additionally, the Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are always to be used with supplemental internal spinal fixation. Additionally, the Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion.

Tritanium® X TL
The Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are intended for intervertebral

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body fusion with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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. These 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 completed six months of non-operative treatment.

Additionally, the Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are always to be used with supplemental internal spinal fixation. Additionally, the Tritanium® X PL Expandable Posterior Lumbar Cage and Tritanium® X TL Expandable Curved Posterior Lumbar Cage are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion.

VLIFT™

Stryker Spine VLIFT™ is a vertebral body replacement system intended to replace a vertebral body or an entire vertebra. It is for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body or vertebra resected or excised during total and partial corpectomy and vertebrectomy procedures due to tumor or trauma (i.e., fracture). For both corpectomy and vertebrectomy procedures, the VLIFT™ system is intended to be used with supplemental internal fixation systems. The supplemental internal fixation systems that may be used with VLIFT™ include, but are not limited to Stryker Spine plate or rod systems (Xia® Spinal System, Spiral Radius 90D, and Trio). The use of bone graft with VLIFT™ is optional.

VLIFT®-s

VLIFT®-s Vertebral Body Replacement System is indicated for use in the cervical spine (C3-C7) and the thoracolumbar spine (T1-L5) in skeletally mature patients for partial or total replacement of a diseased, collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e., fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissue in degenerative disorders.

The VLIFT®-s Vertebral Body Replacement System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The VLIFT®-s Vertebral Body Replacement System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in

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patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The VLIFT®-s Vertebral Body Replacement System is intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.

Ascential IBD PEEKc Spacer

The Ascential IBD PEEKc Spacers are indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Ascential IBD PEEKc Spacers are to be used with autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and are to be implanted via an open, anterior approach.

The Ascential IBD PEEKc Spacer is intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Aero™ AL

The Stryker Spine Aero™ -AL is an intervertebral body fusion device indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The Aero™ - AL Lumbar Cage System is to be implanted via an anterior approach.

The Aero™ - AL Lumbar Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems) in addition to the included fixation anchors.

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Aero™ LL

The Stryker Spine Aero™ -LL is an intervertebral body fusion device indicated for use with autogenous bone graft 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 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The Aero™ -LL Lumbar Cage System is to be implanted via a lateral approach.

The Aero™ -LL Lumbar Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems). In addition, the device may be used with or without the included fixation anchors.

Aero® C

The Stryker Spine AERO®-C Cervical Cage is indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-Tl disc.

DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have six weeks of non-operative therapy.

The AERO®-C Cervical Cage System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach.

The AERO®-C Cervical Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine. In addition, the device must be used with the included fixation anchors.

AVS® Aria

The Stryker Spine AVS® ARIA PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the AVS® ARIA PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

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	The AVS® ARIA PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine. **AVS® Anchor C** The Stryker Spine AVS® Anchor-C Cervical Cage System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The AVS® Anchor-C Cervical Cage is to be used with autogenous bone graft and implanted via an open, anterior approach. The AVS® Anchor-C Cervical Cage must be used with the internal screw fixation provided by AVS® Anchor-C Fixation Screws. This cervical device is to be used in patients who have had six weeks of non-operative treatment. **AVS® Anchor L** The Stryker Spine AVS® Anchor-L is an intervertebral body fusion device indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. The AVS® Anchor-L Lumbar Cage system is to be implanted via an open, anterior approach. The AVS® Anchor-L Lumbar Cage system may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the AVS® Anchor-L Lumbar Cage must be used with the internal screw and plate fixation provided by the AVS® Anchor-L Fixation Screws and Locking Plate. If AVS® Anchor-L is used with less than three or none of the provided screws, then additional supplemental fixation that has been cleared by the FDA for use in the lumbar spine must be used to augment stability. The accompanying Locking Plate must be used anytime the device is used with any number of screws. **AVS® TL (AVS® TL Sterile)** The Stryker Spine AVS® TL PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the

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subject device is used an adjunct to fusion in patients with degenerative disc disease (DDD) and 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 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the AVS® TL PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® TL PEEK Spacers are to be implanted via posterior approach.

The AVS® TL PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems).

AVS® PL

The Stryker Spine AVS® PL and AVS® UniLIF™ PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the AVS® PL and AVS® UniLIF™ PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® PL PEEK Spacers and AVS® UniLIF™ PEEK Spacers are to be implanted via posterior approach.

The AVS® PL PEEK Spacers and AVS® UniLIF™ PEEK Spacers are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems).

AVS® AL (AVS® AL Sterile)

The Stryker Spine AVS® AL and AVS® ALign PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used an adjunct to fusion in patients with degenerative disc disease (DDD) and one level or two contiguous levels from L2 to S1.

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	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 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the AVS® AL and AVS® ALign PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The AVS® AL and AVS® ALign PEEK Spacers are to be implanted via anterior or anterolateral approach. The AVS® AL and AVS® ALign PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine. **AVS® UniLIF** The Stryker Spine AVS® PL and AVS® UniLIF™ PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the AVS® PL and AVS® UniLIF™ PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The AVS® PL PEEK Spacers and AVS® UniLIF™ PEEK Spacers are to be implanted via posterior approach. The AVS® PL PEEK Spacers and AVS® UniLIF™ PEEK Spacers are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems). **AVS® Nav** The Stryker Spine AVS® Navigator PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is 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

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	have up to Grade 1 spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the AVS® Navigator PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The AVS® Navigator PEEK Spacers are to be implanted via a posterior or posterolateral approach. The AVS® Navigator PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine. **AVS® AS** The Stryker Spine AVS® AS PEEK Spacers are indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AVS® AS PEEK Spacers are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and are to be implanted via an open, anterior approach. The AVS® AS PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment. **Monterey™ AL Interbody System** Monterey™ AL Interbody System – Stand-Alone The Stryker Spine Monterey™ AL Interbody System – Stand-Alone (AL Stand-Alone) is an interbody fusion device 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 or two contiguous levels from L2-S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These 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 non-operative therapy. Additionally, the Monterey™ AL Stand-Alone System can be used as adjunct to fusion in patients diagnosed with degenerative scoliosis. The Monterey™ AL Stand-Alone System is intended to be implanted via an anterior approach.

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	The Monterey™ AL Stand-Alone System may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Monterey™ AL Stand-Alone System must be used with the bone screws provided and requires no additional supplemental fixation. If Monterey™ AL Stand-Alone System is used with less than three or none of the provided bone screws, then additional supplemental fixation that has been cleared by the FDA for use in the lumbosacral spine must be used to augment stability. Hyperlordotic implants (>20° lordosis) are intended to be used with supplemental fixation (e.g., posterior fixation). Monterey™ AL Interbody System – Spacer The Stryker Spine Monterey™ AL Interbody System – Spacer (AL Spacer) is an intervertebral body fusion device 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 or two contiguous levels from L2-S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These 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 non-operative therapy. Additionally, the Monterey™ AL Spacer System can be used as adjunct to fusion in patients diagnosed with degenerative scoliosis. The Monterey™ AL Spacer System is intended to be implanted via an anterior approach. The Monterey™ AL Spacer System is intended to be used with supplemental fixation systems that have been cleared by the FDA for use in the lumbosacral spine. **Aleutian IBF System** When used as a cervical intervertebral body fusion device, the Aleutian implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to Tl, for the treatment of cervical disc disease (defined as neck pain of disco genie origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment. When used as a lumbar intervertebral body fusion device, the Aleutian implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S 1, for the treatment of degenerative disc disease (DOD)

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	with up to Grade I spondylolisthesis. ODD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment. When used as vertebral body replacement devices the Aleutian implants are indicated for use in the thoracolumbar spine (Tl to LS) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body, resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aleutian implants are designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. For all the above indications the Aleutian implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems. **Capri Corpectomy Cage System** CAPRI Corpectomy Cages are vertebral body replacement devices intended for use in the cervical and thoracolumbar spine. When used in the cervical spine (C2-T1), CAPRI Static and Expandable cages are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These cages are intended to restore 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, with bone graft used at the surgeon's discretion. When used in the thoracolumbar spine (T1-L5), CAPRI Static and Expandable cages are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor and trauma (i.e. fracture). These are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The interior of the cages can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion. When used in the thoracolumbar spine, the CAPRI Static and Expandable Corpectomy cages are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

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	When used in the cervical spine at one or two levels, the CAPRI Static and Expandable cages are intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation which is cleared by the FDA. **Cascadia Interbody System** 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. **Chesapeake Stabilization System** When used as a cervical intervertebral body fusion device, the CHESAPEAKE Stabilization System implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

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	When used as a lumbar intervertebral body fusion device, the CHESAPEAKE Stabilization System implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The Lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment. The hyperlordotic lumbar implants (i.e., > 15°) must be used with supplemental fixation (i.e., posterior pedicle screw and rod system) cleared for use in the lumbar spine, in addition to the bone screws provided. Otherwise, the Chesapeake Stabilization System implants (i.e., ≤15°) may be used as a stand-alone device, which is intended to be used with the bone screws provided (i.e., 2 or 3 screws for the 2-screw and 3-screw implants, respectively). **Mojave Expandable Interbody System** The MOJAVE Expandable Interbody System 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 (DOD) 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 MOJAVE lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. MOJAVE lumbar implants are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine. **Sahara Stabilization System** The SAHARA Stabilization System 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 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the SAHARA implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. Hyperlordotic (angles > 15°) and Lateral implants must be used with supplemental fixation (i.e., posterior pedicle screw and rod system) cleared

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	for use in the lumbar spine, in addition to the bone screws provided. Additional supplemental fixation (i.e. pedicle screw and rod system) is needed when used as an adjunct to fusion for degenerative scoliosis. Otherwise, the SAHARA Stabilization System implants may be used as a stand-alone device, which is intended to be used with the bone screws provided. **Santorini Corpectomy Cage System** SANTORINI Corpectomy Cages are vertebral body replacement devices intended for use in the cervical and thoracolumbar spine. When used in the cervical spine (C2-T1), SANTORINI cages are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These cages are intended to restore 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, with bone graft used at the surgeon's discretion. When used in the thoracolumbar spine (T1-L5), SANTORINI cages are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor and trauma (i.e. fracture). These cages are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The interior of the cages can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion. When used in the thoracolumbar spine, the Santorini Corpectomy cages are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems. When used in the cervical spine at one or two levels, the SANTORINI Corpectomy Cage System is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation which is cleared by the FDA.
Summary of the Technological Characteristics	The devices in this submission possess the same technological characteristics as their predicate devices; no changes have been made to any of the devices. Therefore, the fundamental scientific technology of the subject devices is the same as previously cleared devices.

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Summary of the Performance Data	MR Compatibility testing per ASTM F2503-13 was performed. The test results demonstrate that the subject devices performance met the prescribed acceptance criteria and is substantially equivalent to the predicate devices.
Conclusion	The subject devices possess the same intended use and technological characteristics as the predicate devices. Therefore, the subject devices are substantially equivalent.