July 17, 2026

Stryker Spine
% Justin Eggleton
Vice President, Global Regulatory Affairs
VB Spine
2 Pearl Ct.
Allendale, New Jersey 07401

Re: K262061
Trade/Device Name: Tritanium® C Anterior Cervical Cage; Tritanium® PL Cage; Tritanium® TL Curved Posterior Lumbar Cage; Aero® -C Cervical Cage System; AVS® Anchor-C Cervical Cage System; AVS® TL PEEK Spacer; AVS® PL PEEK Spacers; AVS® Navigator PEEK Spacer; AVS® AS PEEK Spacer; Monterey™ AL Interbody System; Aleutian IBF System; Cascadia Interbody System; Chesapeake Stabilization System; Sahara Stabilization System; SANTORINI™ Corpectomy Cage System; MOJAVE Interbody System; VLIFT VERTEBRAL BODY REPLACEMENT SYSTEM; AVS® UniLIF PEEK Spacers; CAPRI™ Corpectomy Cage Systems
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE, MAX, OVD, MQP, PLR
Dated: June 18, 2026
Received: June 18, 2026

Dear Mr. Eggleton:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and

adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part

803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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

Sincerely,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K262061

Please provide the device trade name(s).

Tritanium® C Anterior Cervical Cage;
Tritanium® PL Cage;
Tritanium® TL Curved Posterior Lumbar Cage;
Aero®-C Cervical Cage System;
AVS® Anchor-C Cervical Cage System;
AVS® TL PEEK Spacer;
AVS® PL PEEK Spacers;
AVS® Navigator PEEK Spacer;
AVS® AS PEEK Spacer;
Monterey™ AL Interbody System;
Aleutian IBF System;
Cascadia Interbody System;
Chesapeake Stabilization System;
Sahara Stabilization System;
SANTORINI™ Corpectomy Cage System;
MOJAVE Interbody System;
VLIFT VERTEBRAL BODY REPLACEMENT SYSTEM;
AVS® UniLIF PEEK Spacers;
CAPRI™ Corpectomy Cage Systems

Please provide your Indications for Use below.

TRITANIUM® C Anterior Cervical Cage
The Stryker Spine 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 -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 Stryker Spine Tritanium® C Anterior Cervical Cage is to be used with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft or a bone void filler as cleared by FDA for use in intervertebral body fusion, and is to be implanted via an open, anterior approach.
The Stryker Spine Tritanium® C Anterior Cervical Cage is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine.

TRITANIUM® PL Posterior Lumbar Cage
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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.

TRITANIUM® TL Curved Posterior Lumbar Cage
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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.

AERO® -C Cervical Cage System
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-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 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion, 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® Anchor-C CERVICAL CAGE SYSTEM
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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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® TL PEEK Spacers
The VB 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 I 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 PEEK Spacers
The VB Spine AVS® PL 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.
Additionally, the AVS® PL PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.
The AVS® PL PEEK Spacers are to be implanted via posterior approach.
The AVS® PL 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® Navigator PEEK Spacers
The VB 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 I 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 PEEK SPACER
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 back 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 or a bone void filler as cleared by FDA and implanted via an open, anterior approach.
The AVS® AS PEEK 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.

MONTEREY™ AL Interbody System
The VB 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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).
The VB 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 Systems
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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 Aleutian implants are indicated for spinal fusion procedures to be used with autogenous bone graft or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.
When used as vertebral body replacement devices the Aleutian implants are indicated for use in the thoracolumbar spine (T1 to L5) 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 VB Spine Pedicle Screw and Hook Systems, and VB Spine Spinal Plate Systems.

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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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).

SAHARA® Stabilization System
The SAHARA Stabilization System implants are intervertebral body fusion devices indicated for use with auto graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 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.

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 or 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.

MOJAVE Interbody System
The MOJAVE 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 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.

VLIFT VERTEBRAL BODY REPLACEMENT SYSTEM
The VLIFT® system is a device 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, VLIFT® system is intended to be used with supplemental internal fixation systems. The supplemental internal fixation systems that may be used with VLIFT® system 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 the VLIFT® system is optional.

AVS® UniLIF PEEK Spacers
The VB Spine 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. 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 AVS® UniLIF™ PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.
The AVS® UniLIF™ PEEK Spacers are to be implanted via posterior approach.
The 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).

CAPRI™ Corpectomy Cage Systems
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 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 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 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

VB SPINE

510(k) Summary

510(k) Summary: IBDs	
Submitter:	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person :	Name: Kristina Daoud Email: kristina.tawadros@vbspineco.com Secondary Contact: Name: Justin Eggleton Email: justin.eggleton@vbspineco.com
Date Prepared:	June 11, 2026
Trade Names:	1. Tritanium® C Anterior Cervical Cage 2. Tritanium® PL Cage 3. Tritanium® TL Curved Posterior Lumbar Cage 4. Aero®-C Cervical Cage System 5. AVS® Anchor-C Cervical Cage System 6. AVS® TL PEEK Spacer 7. AVS® PL PEEK Spacers 8. AVS® Navigator PEEK Spacer 9. AVS® AS PEEK Spacer 10. Monterey™ AL Interbody System 11. Aleutian IBF System 12. Cascadia Interbody System 13. Chesapeake Stabilization System 14. Sahara Stabilization System 15. SANTORINI™ Corpectomy Cage System 16. MOJAVE Interbody System 17. VLIFT VERTEBRAL BODY REPLACEMENT SYSTEM 18. AVS® UniLIF PEEK Spacers 19. CAPRI™ Corpectomy Cage Systems

510(k) Summary: IBDs	
Common Name:	Intervertebral fusion device with bone graft, cervical Intervertebral fusion device with integrated fixation, cervical Intervertebral fusion device with bone graft, lumbar Intervertebral fusion device with integrated fixation, lumbar Spinal vertebral body replacement device Spinal vertebral body replacement device - cervical
Proposed Class:	Class II
Classification Name:	Intervertebral Body Fusion Device (21 CFR 888.3080) Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)
Product Code:	ODP, MAX, OVD, MQP, PLR, OVE
Predicate Devices:	**Primary Predicate: K221490** 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 **Reference: K240830** Reef TO/TA System; Regatta Lateral System; Explorer TO System; WaveForm C Interbody System; WaveForm TO Interbody System; WaveForm TA Interbody System; FORZA XP Expandable Spacer System; Shoreline ACS Interbody System; Shoreline RT Interbody System; Meridian Interbody System; WaveForm A Interbody System
Device Description:	The previously cleared 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. The

510(k) Summary: IBDs	
	purpose of this submission is to expand the indications of use of the subject devices to include use with FDA-cleared bone void fillers (BVFs).
Indications for Use:	TRITANIUM® C Anterior Cervical Cage The Stryker Spine 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 -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 Stryker Spine Tritanium® C Anterior Cervical Cage is to be used with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft or a bone void filler as cleared by FDA for use in intervertebral body fusion, and is to be implanted via an open, anterior approach. The Stryker Spine Tritanium® C Anterior Cervical Cage is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine. TRITANIUM® PL Posterior Lumbar Cage 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.

510(k) Summary: IBDs	
	TRITANIUM® TL Curved Posterior Lumbar Cage 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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. AERO® -C Cervical Cage System 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-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 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion, 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® Anchor-C CERVICAL CAGE SYSTEM 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

510(k) Summary: IBDs	
	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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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® TL PEEK Spacers The VB 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 I 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 PEEK Spacers The VB Spine AVS® PL 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 I spondylolisthesis at the involved level(s). These

510(k) Summary: IBDs	
	patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the AVS® PL PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The AVS® PL PEEK Spacers are to be implanted via posterior approach. The AVS® PL 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® Navigator PEEK Spacers The VB 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 I 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 PEEK SPACER 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 back 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 or a bone void filler as cleared by FDA and implanted via an open, anterior approach.

510(k) Summary: IBDs	
	The AVS® AS PEEK 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. MONTEREY™ AL Interbody System The VB 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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). The VB 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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

510(k) Summary: IBDs	
	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 Systems 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 Aleutian implants are indicated for spinal fusion procedures to be used with autogenous bone graft or a bone void filler as cleared by FDA for use in intervertebral body fusion 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. When used as vertebral body replacement devices the Aleutian implants are indicated for use in the thoracolumbar spine (T1 to L5) 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.

510(k) Summary: IBDs	
	For all the above indications the Aleutian implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including VB Spine Pedicle Screw and Hook Systems, and VB Spine Spinal Plate Systems. 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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

510(k) Summary: IBDs	
	procedures to be used with autogenous bone graft or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion 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). SAHARA® Stabilization System The SAHARA Stabilization System implants are intervertebral body fusion devices indicated for use with auto graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.

510(k) Summary: IBDs	
	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. 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 or 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

510(k) Summary: IBDs	
	levels, supplemental fixation should include posterior fixation which is cleared by the FDA. MOJAVE Interbody System The MOJAVE 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 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. VLIFT VERTEBRAL BODY REPLACEMENT SYSTEM The VLIFT® system is a device 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, VLIFT® system is intended to be used with supplemental internal fixation systems. The supplemental internal fixation systems that may be used with VLIFT® system 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 the VLIFT® system is optional. AVS® UniLIF PEEK Spacers The VB 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. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These

510(k) Summary: IBDs	
	patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the AVS® UniLIF™ PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The AVS® UniLIF™ PEEK Spacers are to be implanted via posterior approach. The 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). CAPRI™ Corpectomy Cage Systems 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 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 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 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,

510(k) Summary: IBDs	
	supplemental fixation should include posterior fixation which is cleared by the FDA.
Summary of the Technological Characteristics	The subject IBDs are substantially equivalent to the predicate devices. The subject devices have the same intended use, design, materials, operating principles, and performance specifications as their respective predicates. The proposed modification is to expand the indications statement within the subject IBDS to include use of bone void filler as cleared by FDA for use in intervertebral body fusion. This will not impact the safety and efficacy of the subject devices. There is no physical change to the products resulting from this IFU change and no new or significantly changed risks identified as a result. Therefore, the subject devices are substantially equivalent to their respective predicate devices.
Summary of the Performance Data	The expanded indications for use are supported by a clinical and performance testing rationale. No new performance testing was performed.
Conclusion	The subject devices have the same intended use with additions to the indications for use to align with the reference device. Per the rationales detailed in this submission, the updated indications for use for the subject devices are substantially equivalent to their predicate and reference devices.