DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 26, 2015

Stryker Corporation
Garry T. Hayeck, Ph.D.
Senior Regulatory Affairs Specialist
Stryker Spine
2 Pearl Court
Allendale, New Jersey 07401

Re: K143163
Trade/Device Name: AVS® AL and AVS® ALign PEEK Spacers, AVS® PL and AVS® UniLIF PEEK Spacers, AVS® TL PEEK Spacer, AVS® Navigator PEEK Spacer, AVS® ARIA PEEK Spacer, AccuLIF TL and PL Cage, AVS® Anchor-L Spacer, and Aero™-AL Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: October 31, 2014
Received: November 3, 2014

Dear Dr. Hayeck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143163

Device Name
AVS® AL and ALign PEEK Spacers

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 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.

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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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143163

Device Name
AVS® PL and UniLIF PEEK Spacers

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. 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.

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)*
K143163

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 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.

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)*
K143163

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 I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

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)*
K143163

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 I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

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)*
K143163

Device Name
AccuLIF TL and PL Cage

Indications for Use *(Describe)*
The AccuLIF TL and PL Cage are indicated 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. The AccuLIF TL and PL Cages are always to be used with supplemental internal spinal fixation. Additionally, the AccuLIF TL and PL Cages 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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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143163

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 degeneration of the disc confirmed by history and radiographic studies. 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.

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 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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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143163

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 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.

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.

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) Summary: Expanded Indications for Use Stryker Spine Lumbar Intervertebral Body Fusion Devices	
Submitter	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person	Garry T. Hayeck, Ph.D. Senior Regulatory Affairs Specialist Phone: 201-760-8043 Fax: 201-962-4043 E-mail: garry.hayeck@stryker.com
Date Prepared	January 22, 2015
Trade Name	1. AVS® AL and AVS® ALign PEEK Spacers 2. AVS® PL and AVS® UniLIF PEEK Spacers 3. AVS® TL PEEK Spacer 4. AVS® Navigator PEEK Spacer 5. AVS® ARIA PEEK Spacer 6. AccuLIF TL and PL Cage 7. AVS® Anchor-L Spacer 8. Aero™-AL Lumbar Cage System
Common Name	**1.** AVS® AL and AVS® ALign PEEK Spacers Intervertebral fusion device with bone graft, lumbar **2.** AVS® PL and AVS® UniLIF PEEK Spacers Intervertebral fusion device with bone graft, lumbar **3.** AVS® TL PEEK Spacer Intervertebral fusion device with bone graft, lumbar **4.** AVS® Navigator PEEK Spacer Intervertebral fusion device with bone graft, lumbar **5.** AVS® ARIA PEEK Spacer Intervertebral fusion device with bone graft, lumbar **6.** AccuLIF TL and PL Cage Intervertebral fusion device with bone graft, lumbar **7.** AVS® Anchor-L Spacer Intervertebral fusion device with bone graft, lumbar **8.** Aero™-AL Lumbar Cage System Intervertebral fusion device with integrated fixation, lumbar
Proposed Class	**1.** AVS® AL and AVS® ALign PEEK Spacers Class II **2.** AVS® PL and AVS® UniLIF PEEK Spacers Class II **3.** AVS® TL PEEK Spacer Class II **4.** AVS® Navigator PEEK Spacer Class II

	5. AVS® ARIA PEEK Spacer Class II **6.** AccuLIF TL and PL Cage Class II **7.** AVS® Anchor-L Spacer Class II **8.** Aero™-AL Lumbar Cage System Class II
Classification Name, Codification	**1.** AVS® AL and AVS® ALign PEEK Spacers Intervertebral body fusion device , 21 CFR § 888.3080 **2.** AVS® PL and AVS® UniLIF PEEK Spacers Intervertebral body fusion device , 21 CFR § 888.3080 **3.** AVS® TL PEEK Spacer Intervertebral body fusion device , 21 CFR § 888.3080 **4.** AVS® Navigator PEEK Spacer Intervertebral body fusion device , 21 CFR § 888.3080 **5.** AVS® ARIA PEEK Spacer Intervertebral body fusion device , 21 CFR § 888.3080 **6.** AccuLIF TL and PL Cage Intervertebral body fusion device , 21 CFR § 888.3080 **7.** AVS® Anchor-L Spacer Intervertebral body fusion device , 21 CFR § 888.3080 **8.** Aero™-AL Lumbar Cage System Intervertebral body fusion device , 21 CFR § 888.3080
Product Codes	**1.** AVS® AL and AVS® ALign PEEK Spacers MAX **2.** AVS® PL and AVS® UniLIF PEEK Spacers MAX **3.** AVS® TL PEEK Spacer MAX **4.** AVS® Navigator PEEK Spacer MAX **5.** AVS® ARIA PEEK Spacer MAX **6.** AccuLIF TL and PL Cage MAX **7.** AVS® Anchor-L Spacer OVD, MAX **8.** Aero™-AL Lumbar Cage System OVD
Predicate Devices	<u>Primary Predicate:</u> AVS® AL and AVS® ALign PEEK Spacers (K093864)

	Additional Predicates: AVS® PL and AVS® UniLIF PEEK Spacers (K093704) AVS® TL PEEK Spacer (K083661) AVS® Navigator PEEK Spacer (K100865) AVS® ARIA PEEK Spacer (K101051) AccuLIF TL and PL Cage (K141217) AVS® Anchor-L Spacer (K120869) Aero-AL Lumbar Cage System (K133328)
Device Description	**1.** AVS® AL and AVS® ALign PEEK Spacers The AVS® AL (Anterior Large) and AVS® ALign PEEK Spacers are intended for use as interbody fusion devices. They are offered in a variety of lengths, heights and lordotic angles. The hollow, ring shaped implant has serrations on the top and bottom for fixation. The spacers are manufactured from PEEK OPTIMA LT1 and include tantalum markers for visualization. **2.** AVS® PL and AVS® UniLIF PEEK Spacers The AVS® Partial Lumbar (PL) PEEK Spacers and AVS® UniLIF™ PEEK Spacers are intended for use as an aid in spinal fixation. This hollow, rectangular implant is offered in a variety of lengths, heights and lordotic angles to adapt to a variety of patient anatomies. It has serrations on the superior and inferior surfaces of the implant designed to help with fixation, an ergonomically shaped anterior edge, and a flat posterior edge. Radiopaque markers have been embedded within the implant to help allow for visualization in radiographic images. The spacers are manufactured from PEEK OPTIMA LT1 and include tantalum markers for visualization. **3.** AVS® TL PEEK Spacer The AVS® TL PEEK Spacer is intended for use as an aid in spinal fixation. It is offered in both parallel and wedge shapes. The hollow implant has serrations on the top and bottom which are designed to help with fixation. The spacers are manufactured from PEEK OPTIMA LT1 and include tantalum markers for visualization. **4.** AVS® Navigator PEEK Spacer The AVS® Navigator PEEK Spacer is intended for use as an interbody fusion device. It is offered in a variety of lengths, heights and lordotic angles. The hollow implant has serrations on the top and bottom for fixation. Radiopaque markers have been embedded within the implant to help allow for visualization in radiographic images. The spacers are

	manufactured from PEEK OPTIMA LT1 and include tantalum markers for visualization. **5.** AVS® ARIA PEEK Spacer The AVS® ARIA PEEK Spacer is intended for use as an interbody fusion device. It is offered in a variety of lengths, heights and lordotic angles. The hollow, oblong-shaped implant has serrations on the top and bottom for fixation. The spacers are manufactured from PEEK OPTIMA LT1 and include tantalum markers for visualization. **6.** AccuLIF TL and PL Cage The AccuLIF TL and PL Expandable Lumbar Interbody Cages are crescent and rectangular-shaped titanium implants. These implants are intended for use as interbody fusion devices and are offered in a variety of lengths, footprints, and lordotic angles designed to adapt to different patient anatomies. The implants can be expanded in height after insertion in the unexpanded state using the system instrumentation. The implants automatically lock at 1mm increments during expansion. The implants have serrations on the superior and inferior surfaces designed for multidirectional fixation and increased surface area for osteointegration, ergonomically shaped anterior edges to facilitate cage insertion with preservation of endplates and flat posterior edges. The cages have a central opening spanning endplate to endplate for graft containment and to permit fusion through the device. The cages are manufactured from implant grade titanium alloy (Ti-6Al-4V), stainless steel (316 LVM), and silicone rubber (MED-4870). **7.** AVS® Anchor-L Spacer The AVS® Anchor-L Lumbar Cage System consists of a hollow, rectangular-shaped PEEK OPTIMA LT1 cage, titanium alloy (Ti-6Al-4V) bone screws, and a titanium alloy (Ti-6Al-4V) locking plate. Tantalum markers are included for visualization. It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints, and lordotic angles to adapt to varying patient anatomies. The AVS® Anchor-L cage consists of one closed pocket for graft containment and has serrations on the superior and inferior surfaces of the cage. The implant is designed to be used exclusively with the internal supplemental fixation provided. **8.** Aero™-AL Lumbar Cage System

	The Aero™-AL Cage is a hollow, box-shaped PEEK OPTIMA LT1 cage surrounded by a titanium alloy (Ti-6Al-4V) jacket. The PEEK cage portion consists of three closed pockets for graft containment and has serrations on the superior and inferior surfaces of the cage. The cage is designed to be used with the integrated fixation provided (Aero™-AL Fixation Anchors) in addition to supplemental fixation systems cleared for use in the lumbosacral spine. The Aero™-AL Fixation Anchors are constructed from titanium alloy (Ti-6Al-4V) and feature rails that mate with dovetail channels located within the Aero™-AL PEEK cage. Once fully seated into the channels, the anchors are designed to lock into the titanium jacket.
Indications for Use	**1.** AVS® AL and AVS® ALign PEEK Spacers 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 as an adjunct to f usion 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. 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. **2.** AVS® PL and AVS® UniLIF PEEK Spacers 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. 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. 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). **3.** AVS® TL PEEK Spacer 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 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. 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). **4.** AVS® Navigator PEEK Spacer 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 I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. 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. **5.** AVS® ARIA PEEK Spacer 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 I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. The AVS® ARIA PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine. **6.** AccuLIF TL and PL Cage The AccuLIF TL and PL Cage are indicated 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. The AccuLIF TL and PL Cages are always to be used with supplemental internal spinal fixation. Additionally, the AccuLIF TL and PL Cages 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. **7.** AVS® Anchor-L Spacer 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 I 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 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. **8.** Aero™-AL Lumbar Cage System 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 I 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.
Summary of Technological Characteristics	The subject Stryker Spine lumbar intervertebral body fusion devices and the predicate systems share similar design features: • Graft windows for packing autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion • Serrations on the superior and inferior surfaces • Comparable heights, widths, depths, and lordotic angles The purpose of this 510(k) submission is to seek clearance for use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an alternative to autogenous bone graft when the subject device is used as an adjunct to fusion. No changes have been made to the actual implants.
Summary of the Performance Data	Published clinical data for lumbar interbody fusion devices similar to the Stryker Spine lumbar intervertebral body fusion devices that are the subject of this submission was provided in support of this application. The published clinical outcomes demonstrated that the use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion in patients diagnosed with degenerative disc disease as defined above does not adversely affect performance of the system and does not represent a new worst case scenario. No changes were made to the existing devices, nor were any new components added to the system. Therefore, no additional testing

	was required or performed.
Conclusion	The design features, materials used, manufacturing, and sterilization methods are identical to the previously cleared Stryker Spine lumbar intervertebral body fusion devices with the exception of broadening the indications to include the use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion. The data presented in this submission demonstrate that the Stryker Spine lumbar intervertebral body fusion devices that are the subject of this submission with the broadened indications as described above are substantially equivalent to the predicate systems.