



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

Stryker Corporation
Ms. Kristen Meany
Manager, Regulatory Affairs
2 Pearl Court
Allendale, New Jersey 07401

January 20, 2016

Re: K151726

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

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral body fusion device

Regulatory Class: Class II

Product Code: MAX

Dated: December 21, 2015

Received: December 22, 2015

Dear Ms. Meany:

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 Parts 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151726

Page 1 of 9

K151726

Device Name

AVS® AL and AVS® 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.

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

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

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

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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

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

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

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

Indications for Use

510(k) Number (if known)

K151726

Page 2 of 9

K151726

Device Name

AVS® PL and AVS® 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.

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

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

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

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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

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

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

Indications for Use

510(k) Number (if known)

K151726

Page 4 of 9

K151726

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.

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

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

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

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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

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

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

Indications for Use

510(k) Number (if known)

K151726

Page 6 of 9

K151726

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.

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

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

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

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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

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

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

Indications for Use

510(k) Number (if known)

K151726

K151726

Page 8 of 9

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.

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

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

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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

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

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

510(k) Summary: Expanded Indications for Use – Degenerative Scoliosis Stryker Spine Lumbar Intervertebral Body Fusion Devices	
Submitter	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person	Kristen Meany, MS, CQA, RAC Manager, Regulatory Affairs Phone: 201-760-8070 Fax: 201-962-4070 E-mail: kristen.meany@stryker.com
Date Prepared	January 15, 2016
Trade Name	<ol style="list-style-type: none"> 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
Common Name	<ol style="list-style-type: none"> 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
Proposed Class	<ol style="list-style-type: none"> 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
Classification Name, Codification	<ol style="list-style-type: none"> 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

	<p>Intervertebral body fusion device , 21 CFR § 888.3080</p> <p>5. AVS® ARIA PEEK Spacer Intervertebral body fusion device , 21 CFR § 888.3080</p>
Product Codes	<p>1. AVS® AL and AVS® ALign PEEK Spacers MAX</p> <p>2. AVS® PL and AVS® UniLIF PEEK Spacers MAX</p> <p>3. AVS® TL PEEK Spacer MAX</p> <p>4. AVS® Navigator PEEK Spacer MAX</p> <p>5. AVS® ARIA PEEK Spacer MAX</p>
Predicate Devices	<p>Primary Predicate: AccuLIF TL and PL Cage (K143616)</p> <p>Additional Predicates: AVS® AL and AVS® ALign PEEK Spacers (K143163) AVS® PL and AVS® UniLIF PEEK Spacers (K143163) AVS® TL PEEK Spacer (K143163) AVS® Navigator PEEK Spacer (K143163) AVS® ARIA PEEK Spacer (K143163)</p>
Device Description	<p>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.</p> <p>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.</p> <p>3. AVS® TL PEEK Spacer</p>

	<p>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.</p> <p>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.</p> <p>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.</p>
<p>Indications for Use</p>	<p>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 fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.</p> <p>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.</p> <p>Additionally, the AVS® AL and AVS® ALign PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.</p>

	<p>The AVS® AL and AVS® ALign PEEK Spacers are to be implanted via anterior or anterolateral approach.</p> <p>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.</p> <p>2. AVS® PL and AVS® UniLIF PEEK Spacers</p> <p>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.</p> <p>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.</p> <p>Additionally, the AVS® PL and UniLIF™ PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.</p> <p>The AVS® PL PEEK Spacers and AVS® UniLIF™ PEEK Spacers are to be implanted via posterior approach.</p> <p>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).</p> <p>3. AVS® TL PEEK Spacer</p> <p>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.</p> <p>DDD is defined as back pain of discogenic origin with</p>
--	--

	<p>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.</p> <p>Additionally, the AVS® TL PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.</p> <p>The AVS® TL Peek Spacers are to be implanted via posterior approach.</p> <p>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).</p> <p>4. AVS® Navigator PEEK Spacer</p> <p>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.</p> <p>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.</p> <p>Additionally, the AVS® Navigator PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.</p> <p>The AVS® Navigator PEEK Spacers are to be implanted via a posterior or posterolateral approach.</p> <p>The AVS® Navigator PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine.</p>
--	---

	<p>5. AVS® ARIA PEEK Spacer</p> <p>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.</p> <p>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.</p> <p>Additionally, the AVS® ARIA PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.</p> <p>The AVS® ARIA PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine.</p>
Summary of Technological Characteristics	<p>The subject Stryker Spine lumbar intervertebral body fusion devices and the predicate systems share similar design features:</p> <ul style="list-style-type: none"> • 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 <p>The purpose of this 510(k) submission is to seek clearance for use of the Stryker Spine lumbar intervertebral body fusion devices to treat patients diagnosed with degenerative scoliosis. No changes have been made to the actual implants as a result of this submission.</p>
Summary of the Performance Data	<p>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 the lumbar interbody fusion procedures to treat patients diagnosed with degenerative scoliosis 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</p>

	devices; therefore, no additional implant testing was required or performed.
Conclusion	<p>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 Stryker Spine lumbar intervertebral body fusion devices to treat patients diagnosed with degenerative scoliosis.</p> <p>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.</p>