510(k) Summary: AVS® A-LAT PEEK Spacers	
Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Mrs. Kimberly Lane AUG 1 2 2010 Regulatory Affairs Specialist Phone: 201-760-8215 FAX: 201-760-8415 Email: kimberly.lane@stryker.com
Date Prepared	August 11, 2010
Trade Name	Stryker Spine AVS® A-LAT PEEK Spacers
Proposed Class	Class II
Classification Name and Number	Intervertebral body fusion device, 21 CFR 888.3080
Product Code	MAX
Predicate Devices	The AVS® A-LAT PEEK Spacer was shown to be substantially equivalent to the devices listed below: • DePuy AcroMed, Inc. Lumbar I/F Cage® with VSP® Spine System, PMA# P960025 • Stryker Spine AVS® PL PEEK Spacers, 510(k) # K082014 • Globus PATRIOT® Transcontinental® Spacer, 510(k) # K093242 • Stryker Spine AVS® TL PEEK Spacers, 510(k) # K083661 • NuVasive CoRoent® XL Spacers, 510(k)s # K071795 and K081611
Device Description	The AVS® A-LAT Peek Spacers are intervertebral body fusion devices intended for use as an aid in spinal fixation. The AVS® A-LAT PEEK Spacers are rectangular shaped, hollow frame implants with lateral fenestrations, machined from medical grade PEEK OPTIMA LT1 per ASTM F2026. The spacers

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	incorporate five (5) Tantalum (per ASTM F560) marker pins to aid in radiographic visualization. The AVS® A-LAT PEEK Spacers are available in a variety of sizes and angles that allow the surgeon to best choose the size suited to the patient's anatomy and pathology.
Intended Use	The Stryker Spine AVS® A-LAT PEEK Spacers are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. The AVS® A-LAT PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine.
	A description of the subject devices containing the specific information recommended by FDA in the "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" is provided in Section 11 of this 510(k) submission.
Summary of the Technological Characteristics	The subject AVS® A-LAT PEEK Spacers and the predicates share similar design features: • Lateral fenestrations • Serrations on the superior and inferior surfaces • Comparable heights, widths, and angles • Markers for position confirmation when using radiographic

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	imaging Testing in compliance with FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the AVS® A-LAT PEEK Spacers and demonstrated substantially equivalent performance to the identified predicate device systems. The following mechanical tests were performed: • Static Compression (per ASTM F2077) • Dynamic Compression (per ASTM F2077) • Static Compression Shear (per ASTM F2077) • Dynamic Compression Shear (per ASTM F2077) • Subsidence (per ASTM F2267)
Conclusion	The AVS® A-LAT PEEK spacers have demonstrated substantial equivalence in performance, material, indications and design to the identified predicate device systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 12 2010

Stryker Spine
% Ms. Kimberly Lane
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K101051
Trade/Device Name: AVS® A-LAT PEEK Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 04, 2010
Received: August 05, 2010

Dear Ms. Lane:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101051

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Device Name: Stryker Spine AVS® A-LAT PEEK Spacers

Indications For Use:

The Stryker Spine AVS® A-LAT PEEK Spacers are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

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

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K101051