510(k) Summary: AVS® Navigator PEEK Spacers AUG 11 2010

Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Ms. Kimberly Lane Regulatory Affairs Specialist Phone: 201-760-8215 FAX: 201-760-8415 Email: kimberly.lane@stryker.com
Date Prepared	June 10, 2010
Trade Name	Stryker Spine AVS® Navigator 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® Navigator 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® TL PEEK Spacers, 510(k) # K083661, ▪ Stryker Spine AVS® PL PEEK Spacers, 510(k) #s K093704, ▪ K090816, K082014, K080758 and K073470, ▪ LifeSpine Plateau Spacer, 510(k) #K080411.
Device Description	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. Three (3) Tantalum Radiopaque markers have been embedded within the implant to help allow for visualization in radiographic images.

Intended Use	The Stryker Spine AVS® Navigator 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® 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.
Summary of the Technological Characteristics	Testing in compliance with FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the AVS® Navigator PEEK Spacers and demonstrated substantial equivalent performance characteristics to the identified predicate device systems. The following mechanical tests were performed: • Static Compression • Dynamic Compression • Static Compression Shear • Dynamic Compression Shear • Subsidence

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 11 2010

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

Re: K100865
Trade/Device Name: Stryker Spine AVS® Navigator 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,

Barbara Buehrs

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

AUG 11 2010

510(k) Number (if known): K100865

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Indications For Use:

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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 K100865