Special 510(k) Summary of Safety and Effectiveness: Line Extension to the AVS™ PL PEEK Spacer System

Proprietary Name:	AVS™ PL PEEK Spacer System
Common Name:	Spinal Fixation Appliances
Proposed Regulatory Class:	Class II Spinal Vertebral Body Replacement Device, 21 CFR 888.3060
Device Product Code:	MQP
For Information contact:	Simona Voic Regulatory Affairs Project Manager 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8145 Fax: (201) 760-8345 Email: Simona.Voic@stryker.com
Date Summary Prepared:	July 25, 2006
Predicate Device	Stryker Spine AVS™ PL PEEK Spacer (K050624)
Predicate Device Information	The AVS™ PL Peek Spacer is a rectangular shaped, hollow frame implant with lateral fenestrations, machined from medical grade PEEK OPTIMA LT1. The spacer incorporates two (2) Tantalum marker pins to aid in radiographic visualization. The AVS™ PL Peek Spacer System is comprised of six (6) different

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	sized footprints with a variety of heights and lordotic angles. The AVS™ PL Peek System was determined substantial equivalent via K040731 and K050624.
Description of Device Modification	This Special 510(k) premarket notification is intended to introduce additional sizes of the AVS™ PL Peek Spacer.
Intended Use	The Stryker Spine AVS™ PL PEEK Spacer is a vertebral body replacement indicated for use in the thoraco-lumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised during partial and total vertebrectomy procedures due to tumor or trauma, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. It is recommended to pack bone graft material inside the implant. The Stryker Spine AVS™ PL PEEK Spacer is intended for use with supplemental fixation. The supplemental fixation systems that may be used with the Stryker Spine AVS™ PL PEEK Spacer include, but are not limited to, Stryker Spine plate or rod systems (XIA, Spiral Radius 90D, and Trio).

Summary of the Technological Characteristics	Documentation is provided which demonstrates the additional sizes of the Stryker Spine AVS™ PL PEEK Spacer to be substantially equivalent to their predicate device in terms of its material, design, and indications for use. Compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 was also demonstrated for the subject spacers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2006

Stryker Spine
% Ms. Simona Voic
Regulatory Affairs Project Manager
2 Pearl Court
Allendale, New Jersey 07401

Re: K062132
Trade/Device Name: AVS™ PL PEEK Spacer System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: July 25, 2006
Received: July 26, 2006

Dear Ms. Voic:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This

letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062132

Indications for Use

510(k) Number (if known): _____

Device Name: AVS™ PL PEEK Spacer System

Indications for Use:

The Stryker Spine AVS™ PL PEEK Spacer is a vertebral body replacement indicated for use in the thoraco-lumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised during partial and total vertebrectomy procedures due to tumor or trauma, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

It is recommended to pack bone graft material inside the implant.

The Stryker Spine AVS™ PL PEEK Spacer is intended for use with supplemental fixation. The supplemental fixation systems that may be used with the Stryker Spine AVS™ PL PEEK Spacer include, but are not limited to, Stryker Spine plate or rod systems (XIA, Spiral Radius 90D, and Trio).

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062132