510(k) Summary of Safety and Effectiveness: Stryker Spine AVS™ PL PEEK Spacer

Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Ms. Simona Voic Regulatory Affairs Project Manager Phone: 201- 760-8145 FAX: 201- 760-8345 Email: Simona.Voic@stryker.com
Date Prepared	March 9, 2005
Trade Name	Stryker Spine AVS™ PL PEEK Spacer
Classification Name and Number	Spinal Vertebral Body Replacement Device, 21 CFR 888.3060
Product Code	MQP
Purpose of the premarket notification	The purpose of this premarket notification is to add indications and new implant sizes to the previously cleared Stryker Spine Vertebral Spacer.
Predicate Devices	1) Stryker Spine Vertebral Spacer (K040731) 2) Stryker Spine AVS™ TL PEEK Spacer (K042571) 3) Medtronic Sofamor Danek VERTE-STACK™ Spinal System (K031780) 4) DePuy Surgical Titanium Mesh™ (K003043) 5) Surgical Dynamics Mesh Cage System (K003709)
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 procedure 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 Stryker Spine AVS™ PL PEEK Spacer to be substantially equivalent to its predicate devices in terms of its material, sizes, and indications for use. Testing to demonstrate compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 was completed for the Stryker Spinal AVS™ PL PEEK Spacer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1 2005

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

Re: K050624
Trade/Device Name: Stryker Spine 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: March 9, 2005
Received: March 11, 2005

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.

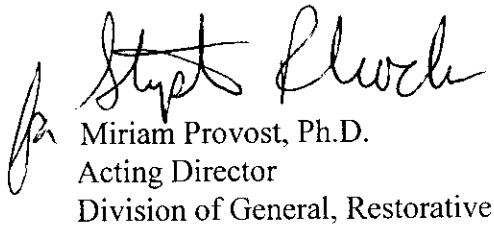
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050624

Indications for Use

510(k) Number (if known):_____

Device Name: Stryker Spine AVS™ PL PEEK Spacer

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 Vertebral Spacer include, but are not limited to, Stryker Spine plate rod 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 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 General, Restorative, and Neurological Devices

510(k) Number K050624