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K042571

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

510(k) Submitter:
Stryker Spine
2 Pearl Court, Allendale, New Jersey 07401

510(k) Contact:
Ms. Simona Voic
Regulatory Affairs Project Manager
Telephone: 201-760-8145/ Fax: 201-760-8345
Email: Simona.Voic@stryker.com

Date Prepared:
December 30, 2004

Proprietary Trade Name:
Stryker Spine AVS™ TL Peek Spacer

Common Name:
Vertebral Body Replacement

Classification Name and Reference:
Spinal Intervertebral Body Fixation Orthosis
21 CFR 888.3060

Device Panel/ Product Code:
MQP: Spinal Vertebral Body Replacement Device

Predicate Devices:
Stryker Spine Vertebral Spacer [K040731]
DePuy AcroMed™, Inc. Surgical Titanium Mesh™ System [K003043]
Medtronic Sofamor Danek VERTE-STACK™ Spinal System [K031780]
Rezaian Spinal Fixator [K841189]

Product Description:
The Stryker Spine AVS™ TL Peek Spacer inserts between vertebral bodies in the anterior thoracic and lumbar spine. The device is intended for vertebral body replacement to aid in thesurgical correction and stabilization of the spine. The construct is intended for use with supplemental fixation. The device is manufactured from Polyetheretherketone (PEEK) OPTIMA LT1 as described by ASTM F-2026-02. The three (3) Tantalum markers used for this product are made to the standard of ASTM F-560.

Indications:
The Stryker Spine AVS™ TL 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™ TL PEEK Spacer is intended for use with supplemental fixation. The supplemental fixation systems that may be used with the Stryker Spine AVS™ TL 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 was provided which demonstrates the Stryker Spine AVS™ TL 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 "Spinal System 510(k)s", May 3, 2004 was completed for the Stryker Spine AVS™ TL PEEK Spacer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

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

Re: K042571
Trade/Device Name: Stryker Spine AVS™ TL PEEK Spacer
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: January 7, 2005
Received: January 10, 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.

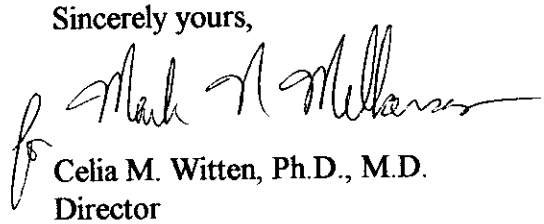
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (21 CFR 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042571

Device Name: Stryker Spine AVS™ TL PEEK Spacer

Indications For Use:

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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)

Mark N Milhouse

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

510(k) Number K042571