K091946

SEP 25 2009

510(k) Summary: Stryker Spine VLIFT®-s Vertebral Body Replacement System

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 26, 2009
Trade Name	Stryker Spine VLIFT®-s Vertebral Body Replacement System
Proposed Class	Class II
Classification Name and Number	Spinal Intervertebral Body Fixation Orthosis, 21 CFR 888.3060
Product Code	MQP
Predicate Devices	Stryker Spine VLIFT® Vertebral Body Replacement System [K060506], DePuy X-MESH™ Expandable Cage System [K080568], Synthes Spine Synex™ II Spacer [K061891], Surgical Dynamics™ Mesh Cage System, [K003709] and DePuy AcroMed Surgical Titanium Mesh™ [K003043] Product Code MQP, Class II
Device Description	The VLIFT®-s Distractible *In-situ* (DIS) Vertebral Body Replacement system is intended for use as an aid in spinal fusion and consists of a single, pre-assembled distractible implant. The hollow cylindrical center may be adjusted continuously via an inner concentric ring. The hollow core of the cage allows for packing bone graft. The use of bone graft with VLIFT®-s is optional. As the implant is distracted via its inner concentric ring, additional, slotted openings appear. The VLIFT®-s cages are available in various diameters and heights.

K091946

	Modular end caps snap into each end of the VLIFT®-s implant. Serrated teeth at the rim of the end cap attachments help to anchor the implant to the end plates of the vertebral bodies. The VLIFT®-s end caps are available in both flush and contoured designs and are offered in a variety of angles. Extension pieces are available for each diameter for the VLIFT®-s implants. Extension pieces may be used to achieve the desired height. The use of extension pieces is optional.
Intended Use	The VLIFT®-s system is a device intended to replace a vertebral body or an entire vertebra. It is for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body or vertebra resected or excised during total and partial corpectomy and vertebrectomy procedures due to tumor or trauma (i.e., fracture). For both corpectomy and vertebrectomy procedures, VLIFT®-s system is intended to be used with supplemental internal fixation systems. The supplemental internal fixation systems that may be used with VLIFT®-s system include, but are not limited to, Stryker Spine plate or rod systems (e.g., Xia® Spinal System, Radius® Spinal System, Mantis® Percutaneous Spinal System, Thor® Plating System, Trio®+Spinal System). The use of bone graft with VLIFT®-s system is optional.
Summary of the Technological Characteristics	Documentation is provided which demonstrates the Stryker Spine VLIFT®-s Vertebral Body Replacement System to be substantially equivalent to its predicate devices in terms of its material, design, indications for use, and mechanical performance. Testing to demonstrate compliance with FDA's *Guidance for Spinal System 510(k)'s* issued May 3, 2004 was completed for the Stryker Spine VLIFT®-s Vertebral Body Replacement System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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

SEP 25 2009

Re: K091946
Trade/Device Name: Stryker Spine VLIFT®-s Vertebral Replacement System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: June 26, 2009
Received: June 30, 2009

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.

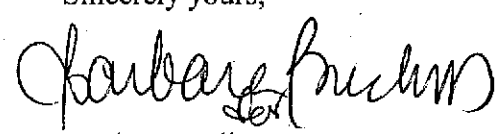
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 (240) 276-3150 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): K091946

Device Name: Stryker Spine VLIFT®-s Vertebral Body Replacement System

Indications For Use:

The VLIFT®-s system is a device intended to replace a vertebral body or an entire vertebra. It is for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body or vertebra resected or excised during total and partial corpectomy and vertebrectomy procedures due to tumor or trauma (i.e., fracture).

For both corpectomy and vertebrectomy procedures, VLIFT®-s system is intended to be used with supplemental internal fixation systems. The supplemental internal fixation systems that may be used with VLIFT®-s system include, but are not limited to, Stryker Spine plate or rod systems (e.g., Xia® Spinal System, Radius® Spinal System, Mantis® Percutaneous Spinal System, Thor® Plating System, Trio®+Spinal System). The use of bone graft with VLIFT®-s system is optional.

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)

Pg 1 of 1