MAY 25 2006

510(k) Summary of Safety and effectiveness
Stryker Spine VLIFT™ Vertebral Body Replacement System

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| Submitter: | Stryker Spine<br>2 Pearl Court<br>Allendale, New Jersey 07401 |
| Contact Person | Ms. Simona Voic<br>Regulatory Affairs Project Manager<br>Phone: 201-760-8145<br>FAX: 201-760-8345<br>Email: simona.voic@stryker.com |
| Date Prepared | May 15, 2006 |
| Trade Name | Stryker Spine VLIFT™ Vertebral Body Replacement System |
| Proposed Class | Class II |
| Classification Name and Number | Spinal Intervertebral Body Fixation Orthosis<br>21 CFR 888.3060 |
| Product Code | MQP |
| Predicate Devices | 1) Stryker Spine AVS™ PL Peek Spacer (K050624), Product Code MQP, Class II<br>2) Synthes Spine Synex™ Spacer System (K003836), Product Code MQP, Class II<br>3) Surgical Dynamics Mesh Cage System (K003709), Product Code MQP, Class II<br>4) DePuy Harms Mesh Cage (K003043), Product Code MQP, Class II |
| Device Description | Stryker Spine VLIFT™ is a vertebral body replacement system, intended for use as an aid in spinal fusion.<br><br>The VLIFT™ vertebral body replacement system consists of a single, pre-assembled cylindrically shaped titanium cage, with a distractible or retractable center. The hollow core of the cage allows for packing bone graft. The use of bone graft with VLIFT™ is optional.<br><br>The VLIFT™ cages are available in two (2) diameters (18 mm and 22 mm) and cover a range of heights from 18.5 to 58.5 mm. The end caps are available in a variety of round angled shapes to better match the sagittal angle of the spinal segment.<br><br>The optional extension pieces are offered for both the 18mm and 22mm diameter cages. Each extension piece adds 15mm to the construct height. One or two extensions can be assembled to the implant, which creates a maximum construct height of 88.5 mm. |

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| Intended Use | Stryker Spine VLIFT™ is a vertebral body replacement system 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, the VLIFT™ system is intended to be used with supplemental internal fixation systems. The supplemental internal fixation systems that may be used with VLIFT™ include, but are not limited to Stryker Spine plate or rod systems (Xia® Spinal System, Spiral Radius 90D, and Trio). The use of bone graft with VLIFT™ is optional. |
| Summary of the Technological Characteristics | Documentation is provided which demonstrates the Stryker Spine VLIFT™ 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 May 3, 2004 was completed for the Stryker Spine VLIFT™ Vertebral Body Replacement System. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2006

Stryker Spine
c/o Ms. Simona Voic
2 Pearl Court
Allendale, New Jersey 07401

Re: K060506
Trade Name: VLIFT™ Vertebral Body Replacement System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: May 2, 2006
Received: May 3, 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
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): K060506

Device Name: Stryker Spine VLIFT™ Vertebral Body Replacement System

Indications For Use:

Stryker Spine VLIFT™ is a vertebral body replacement system 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, the VLIFT™ system is intended to be used with supplemental internal fixation systems. The supplemental internal fixation systems that may be used with VLIFT™ include, but are not limited to Stryker Spine plate or rod systems (Xia® Spinal System, Spiral Radius 90D, and Trio). The use of bone graft with VLIFT™ 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)

(Division Sign-Off)
Division of General, Restora[illegible]
and Neurological Devices

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