510(k) Summary of Safety and Effectiveness: MANTIS™ Spinal System

SEP 19 2006

Proprietary Name:	MANTIS™ Spinal System
Common Name:	Spinal Fixation Appliances
Proposed Regulatory Class:	Class III
Device Product Code:	Pedicle Screw Spinal System, 21 CFR 888.3070 87 MNH: Spondylolisthesis Spinal Fixation System 87 MNI: Orthosis, Spinal, Pedicle Fixation 87 NKB: Orthosis, Spinal Pedicle Fixation, for Degenerative Disc Disease
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 31, 2006

Predicate Device Identification

The predicate devices are:

Stryker Spine Xia® Titanium Spinal System polyaxial cannulated screws (510(k) #K043473 and #K060361),

Stryker Spine Xia® Titanium Spinal System polyaxial screws (K002858, K013823),

Stryker Spine Straight and pre-bent rods (510(k) #K951725, #K984251 and #K060361),

Sofamor Danek CD Horizon® Spinal System (K001255), and

DePuy Spine, Inc. VIPER™ Spine System (K061520).

Device Description

This 510(k) submission is intended to introduce the MANTIS™ Spinal System. The MANTIS™ Spinal System includes cannulated polyaxial screw and straight or pre-bent rod components that can be used via a percutaneous surgical approach. The components are available in a variety of diameters and lengths in order to accommodate patient anatomy and are fabricated from titanium alloy. The implants will be provided non-sterile.

Intended Use:

The MANTIS™ Spinal System is intended for percutaneous, posterior, non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

Summary of the Technological Characteristics:

Documentation is provided which demonstrates that the Stryker Spine MANTIS Spinal System is substantially equivalent to its predicate devices in terms of its material, design, and indications for use, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

SEP 19 2006

Re: K061813
Trade/Device Name: MANTIS™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: MNH, MNI, NKB
Dated: June 26, 2006
Received: June 27, 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

Indications for Use

510(k) Number (if known): K061813

Device Name: MANTIS™ Spinal System

Indications for Use:

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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)

Marilyn Mechan

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

510(k) Number K061813