**Special 510(k) Summary:**
**MANTIS® Spinal System**

K073151

| | |
|---|---|
| Proprietary Name: | MANTIS® Spinal System |
| Common Name: | Spinal Fixation Appliances |
| Proposed Regulatory Class: | Class III |
| | Pedicle Screw Spinal System, 21 CFR 888.3070 |
| Device Product Code: | 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: | Curtis Truesdale |
| | Regulatory Affairs Project Manager |
| | 2 Pearl Court |
| | Allendale, NJ 07401 |
| | Telephone: (201) 760-8029 |
| | Fax: (201) 760-8229 |
| | Email: curtis.truesdale@stryker.com |
| Date Summary Prepared: | October 18, 2007 |

DEC 18 2007

## Predicate Device Identification

The predicate device is the existing Stryker Spine MANTIS Spinal System (Cleared through 510(k) #K061813), Stryker Spine Xia® Titanium Spinal System (cleared through 510(k) #K013823, #K043473, K002858, K060361) and Stryker Spine Osteonics Spinal System (cleared through 510(k) #K951725).

## Description of Device Modification

This Special 510(k) submission is intended to introduce a line extension to the MANTIS Spinal System, which entails additional diameter size cannulated polyaxial screw components as well as additional straight rod components in a variety of lengths. Modifications were made to the existing MANTIS Spinal System (K061813) to render the new components. The MANTIS Spinal System will include cannulated polyaxial screw, pre-bent rod and straight rod components that can be used via either a percutaneous surgical approach or a standard open approach.

**Intended Use:**

The MANTIS Spinal System is intended for 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.

**Statement of Technological Comparison:**

Testing has demonstrated that the additional screw and rod components have equivalent mechanical properties to the predicate Stryker Spine Xia® Titanium Spinal System screws and rod components and the Stryker Spine Osteonics Spinal System. Both the new components and the existing system components of the MANTIS are intended to address the same indications for use. Both the new components and the existing components of MANTIS System are made from the same materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2007

Stryker Instruments
% Stryker Spine
Mr. Curtis Truesdale
2 Pearl Court
Allendale, NJ 07401

Re: K073151
Trade/Device Name: Mantis Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Names: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNH, MNI
Dated: November 7, 2007
Received: November 8, 2007

Dear Mr. Truesdale:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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): K073151

Device Name: MANTIS® Spinal System, Line Extension

Indications for Use:

The MANTIS® Spinal System is intended for 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.

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)

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

510(k) Number K073151