AUG 2 4 2010

# STRYKER SPINE

**Special 510(k) Summary of Safety and Effectiveness:**
**MANTIS® Spinal Systems**
**Line Extension**

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| Proprietary Name: | MANTIS® Spinal System and MANTIS® Redux Spinal System |
| Common Name: | Spinal Fixation Appliances |
| Classification Name and Reference: | 1) Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060<br>2) Pedicle Screw Spinal System, 21 CFR §888.3070 (b) (1) & (b) (2) |
| Device Product Code: | NKB, MNH, MNI, KWQ |
| Proposed Regulatory Class: | Class III |
| For Information contact: | Curtis Truesdale<br>Regulatory Affairs Project Manager<br>2 Pearl Court<br>Allendale, NJ 07401<br>Telephone: (201) 760-8296<br>Fax: (201) 760-8496<br>Email: Curtis.Truesdale@Stryker.com |
| Date Summary Prepared: | August 6, 2010 |
| Predicate Devices | ▪ Stryker Spine MANTIS® Spinal System and MANTIS® Redux Spinal System, K092631;<br>▪ Stryker Spine Xia® II Spinal System, K063428;<br>▪ Stryker Spine Xia Spinal System, K002858, K013823, K043473;<br>▪ Stryker Spine Osteonics Spinal System, K951725. |

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| Description of Device Modification | This 510(k) is intended to introduce a line extension to the existing MANTIS® Redux Spinal System. The line extension consists of additional sizes of the MANTIS® Redux Long Arm Polyaxial Screws. The additional sizes include the 7.5 mm and 8.5 screw diameter, ranging 30 – 90 mm in length for the MANTIS Redux Spinal System. No modifications were made to the MANTIS Spinal System. |
| Intended Use | The MANTIS® Spinal System and MANTIS® Redux Spinal System is intended for percutaneous, posterior, non-cervical pedicle and non-pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for the following indications:<br>▪ Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);<br>▪ Spondylolisthesis;<br>▪ Trauma (i.e., fracture or dislocation);<br>▪ Spinal stenosis;<br>▪ Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);<br>▪ Tumor;<br>▪ Pseudoarthrosis; and<br>▪ Failed previous fusion.<br>The Titanium and Vitallium® rods from the Stryker Spine RADIUS® Spinal System are intended to be used with the other components of MANTIS® Spinal System and MANTIS® Redux Spinal System. |
| Summary of the Technological Characteristics | The Stryker Spine MANTIS® Redux Spinal System, with the incorporation of the subject components, is substantially equivalent to the predicate devices in terms of material, design, and indications for use. Static Compression Bending testing, Static Torsion testing and Fatigue Compression Bending testing per ASTM F1717 were conducted on the subject components. The results obtained from these tests were compared to those of a predicate system to demonstrate substantial equivalence, as recommended by the "Guidance for Industry & FDA Staff Spinal System 510(k)s, May 3, 2004." |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Spine
% Mr. Curtis Truesdale
Regulatory Affairs Project Manager
2 Pearl Court
Allendale, New Jersey 07401

AUG 2 4 2010

Re: K102235
Trade/Device Name: MANTIS® Spinal System and MANTIS® Redux Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWQ
Dated: August 06, 2010
Received: August 09, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buehrn

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102235

# Indications for Use

510(k) Number (if known): K102235

Device Name: MANTIS® Spinal System and MANTIS® Redux Spinal System

Indications for Use:

The MANTIS® Spinal System and MANTIS® Redux Spinal System is intended for percutaneous, posterior, non-cervical pedicle and non-pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion 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.

The Titanium and Vitallium rods from the Stryker Spine RADIUS® Spinal System are also intended to be used with other components of the MANTIS® Spinal System and MANTIS® Redux Spinal System.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102235