DEC 7 2012

Special 510(k) Summary:
ES2™ Spinal System - Line Extension of MANTIS® & MANTIS® Redux

Proprietary Name:	ES2™ Spinal System
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	1) Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060 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:	Soraya King Regulatory Affairs Specialist 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8296 Fax: (201) 962-4296 Email: Soraya.King@Stryker.com
Date Summary Prepared:	December 6, 2012
Predicate Devices	▪ Stryker Spine MANTIS® Redux Spinal System, K092631 and K102235
Description of Device Modification	This 510(k) is intended to introduce an extension to the existing MANTIS® Redux Spinal System. The proposed line extension pertains to the integration of the retractor blades to the removable Tab portion of screw head. The MANTIS® Redux Spinal System with the integrated blades will also be rebranded as the ES2™ Spinal System. This submission also seeks clearance of the ES2™ Spinal System with the powered accessory instruments cleared through 510(k) submissions K111478 and K120434
Indication for Use	The ES2™ 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, MANTIS® Redux Spinal Systems and ES2™ Spinal System.

Indication & Intended Use with Powered Instruments

Intended Use:

To facilitate the placement of pedicle screws using the power technique (corded and cordless), the use of the Stryker Spine Power Adaptor is intended for exclusive use with the Stryker Instruments Hudson Modified Trinkle Reamer and the Stryker Instruments CD3 Cordless Driver 3 and the Stryker Instruments RemB Universal Driver. When the power adaptors are attached, the CD3 Cordless Driver 3 and RemB Universal Driver provide power (corded and cordless) to rotate screwdrivers for the insertion of pedicle screws.

Pedicle screws from select Stryker Spine implant systems may be implanted in the skeletally mature non-cervical spine using powered (corded and cordless) instrumentation. The systems included are the family of Xia Spinal Systems (Xia Stainless Steel, Xia II, Xia Anterior, and Xia Precision), Xia 3 Spinal System, Xia 4.5 Spinal System, Radius Spinal System and MANTIS® Spinal System, MANTIS® Redux Spinal System and the ES2™ Spinal System.

Indications for Use:

The Xia Spinal System is intended for anterior/anteriolateral and posterior, non-cervical pedicle and non-pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (DDD) (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; curvature (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The XIA 4.5, Xia 3, Radius Spinal Systems are intended for use in the non-cervical spine. When used as an anterior/anteriolateral and posterior, non-cervical pedicle and non-pedicle fixation system, the Xia 3, XIA 4.5, Xia 3, and Radius Spinal Systems are intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD) (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 MANTIS® Spinal System, MANTIS® Redux Spinal System and ES2™ 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.

Summary of the Technological Characteristics	The Stryker Spine ES2™ Spinal Systems, with the incorporation of the subject components, is substantially equivalent to the predicate devices in terms of material, design, and indications for use. Engineering analysis and testing to demonstrate compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 were completed for the systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

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

Letter dated: December 7, 2012

Re: K122845
Trade/Device Name: ES2™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP
Dated: November 14, 2012
Received: November 15, 2012

Dear Ms. King:

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,

Mark N. Melkerson

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

Enclosure

Indications for Use

510(k) Number (if known): _K122845_____

Device Name: ES2™ Spinal System

Indications for Use:

The ES2™ Spinal System is intended for percutaneous, posterior, non-cervical 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),
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- Tumor,
- Pseudoarthrosis, and
- Failed previous fusion.

The Titanium and Vitallium® rods from the Stryker Spine RADIUS®, MANTIS® and MANTIS® Redux Spinal Systems are intended to be used with the other components of the ES2™ Spinal System.

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

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K122845

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): __K122845_____

Device Name: Power Adaptor Instrument Accessory

Intended Use:

To facilitate the placement of pedicle screws using the power technique (corded and cordless), the use of the Stryker Spine Power Adaptor is intended for exclusive use with the Stryker Instruments Hudson Modified Trinkle Reamer and the Stryker Instruments CD3 Cordless Driver 3 and the Stryker Instruments RemB Universal Driver. When the power adaptors are attached, the CD3 Cordless Driver 3 and RemB Universal Driver provide power (corded and cordless) to rotate screwdrivers for the insertion of pedicle screws.

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Indications for Use:
The Xia Spinal System is intended for anterior/anteriolateral and posterior, non-cervical pedicle and non-pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (DDD) (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; curvature (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The XIA 4.5, Xia 3, Radius Spinal Systems are intended for use in the non-cervical spine. When used as an anterior/anteriolateral and posterior, non-cervical pedicle and non-pedicle fixation system, the Xia 3, XIA 4.5, Xia 3, and Radius Spinal Systems are intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD) (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 MANTIS® Spinal System, MANTIS® Redux Spinal System and ES2™ 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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K122845