MAR - 8 2012

510(K) SUMMARY

1.1 Applicant

Stryker Spine
2 Pearl Court.
Allendale, NJ 07401
Phone: (201)-760-8206
Fax: (201)-760-8406
E-mail:tiffani.rogers@stryker.com

Contact Information:

Paula E. Bulger Regulatory Affairs Consultant
Stryker Spine
Two Pearl Court
Allendale, NJ 07401
Phone: (201)-760-3476
Fax: (201)-760-8406
E-mail:paula.bulger@stryker.com

1.2 Device Trade Name:

Power Adaptor Instrument Accessory

1.3 Device Common Name:

Spinal Fixation Appliances, Instrument Accessory

1.4 Establishment Registration Number

3004024955

1.5 Manufacturer Address

Stryker Spine
Zone Industrielle Demarticot
Cestas, France 33610
Phone: + 33 577 97 08 40

1.5.1 *Manufacturer Establishment Number:*

9617544

1.6 Device Classification:

Stryker Spine Power Adaptor Instrument Accessory Device (new) is a Class III device and is classified by FDA under Pedicle Screw Spinal System, 21 CFR §888.3070 (b) (1) & (b) (2). The FDA Product Codes are NKB, MNH, MNI.

1.7 Device Description/Modification:

The line extension, which is the subject of this 510(k), consists of the addition of a power adaptor instrument accessory. The power adaptor is intended to facilitate the insertion of pedicle screws using the CD3 Cordless Driver 3 powered instrument. The STRYKER Spine Power Adaptor instrument, currently used with the RemB Universal Driver (corded), Power Adaptor (K111478) has the same design and function, differ only with respect to the power source used to operate (4 volt battery vs. Controller interface). Verification activities for fatigue insertion, interface and functional compatibility and comparison testing for profile and weight using the RemB Universal Driver, Power Adaptor (K111478) were found to be equivalent, all test reports are found in **Section 18.3**. This 510(k) supports a labeling update to include the option for pedicle screw insertion using cordless powered instrumentation (in addition to the existing manual and corded power insertion technique). To facilitate the insertion of pedicle screws using the power technique, the use of the Stryker Spine Power Adaptor is intended for exclusive use with the Stryker Instruments Hudson Modified Trinkle Reamer and the CD3 Cordless Driver 3, identical to the RemB Universal Driver (corded) Power Adaptor (K111478). The adaptors serve as a mechanical interface between the power driver and screwdriver instrument. When the adaptors are attached, the CD3 Cordless Driver 3 provides appropriate power to rotate screw drivers for the insertion of pedicle screws. No changes have been made to the indications for use of the associated thoracolumbar spinal implant systems: Xia Spinal System (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. The indications for use of each spinal system remain consistent with their most recent 510(k) clearance.

1.8 Indications for Use

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 Systems.

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 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.

1.9 Predicate Devices

- Stryker Spine RemB Universal Driver, Power Adaptor, K111478
- Stryker Spine XIA Spinal Systems, K060361;
- Stryker Spine XIA 3 Spinal System, K091291;
- Stryker Spine XIA 4.5 Spinal System, K092605;
- Stryker Spine RADIUS Spinal System, K101144;
- Stryker Spine MANTIS Spinal System, K102235;
- Stryker Instruments CD3 Cordless Driver System, K943323.

1.10 Summary of Technological Characteristics

A Risk Assessment was conducted using both the RemB Universal Driver (corded) Power Adaptor (K1114780) and CD3 Cordless Driver 3 Power Adaptor; which identified an appropriate parallel testing plan. Comparison verification and validation testing was based on the Risk Assessment using the RemB Corded Power Adaptor (K1114780) and CD3 Cordless Driver 3 Power Adaptor, verification activities performed and reported for RemB Universal Driver (corded) (K111478) are the identical reports submitted for CD3 Cordless Driver 3 Power Adaptor. Verification activities consisted which consisted of the following: bench testing for fatigue insertion over a simulated three year usage period, interface and functional compatibility of the Power Adaptor against the existing screwdrivers currently used for placement of pedicle screws, and comparison testing for profile and weight. Test results demonstrated that the subject device can withstand screw loading and screw insertion during normal use without loss of function. Additional, bench testing results confirmed that the CD3 Cordless Driver 3Power Adaptor device is compatible with existing screwdriver instruments. No significant differences were observed concerning the surgeon interface for usability and ergonomics between the two hand pieces, and safety evaluation testing of the CD3 Cordless Driver 3 Power Adaptor pedicle screw insertion technique under simulated use conditions presented no quality/accuracy issues for screw placement. Additionally, the weight differences were considered modest and both size and shape were of similar design. Verification testing (including test methods, materials and results) are described in TRP000002163 report title "Power Screw Insertion Power Adaptor

Fatigue Verification." and DSGN-fm-5303 report title "Verification Power Screw Insertion Fatigue Verification Technician Summary." These reports are provided in **Section 18.3.**

The Stryker Spine CD3 Cordless Driver 3 Power Adaptor and RemB Universal Driver Power Adaptor (K1114780) are identical in design and performance and differ only with respect to the power source used for operation.

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
% Ms. Paula Bulger
Regulatory Affairs Consultant
2 Pearl Street
Allendale, New Jersey 07401

MAR - 8 2012

Re: K120434
Trade/Device Name: Power Adaptor Instrument Accessory
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system (accessory instrument)
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: February 9, 2012
Received: February 13, 2012

Dear Ms. Bulger:

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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K120434

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.

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 Systems.

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 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.

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120434