STRYKER SPINE

JUL - 8 2010

Special 510(k) Summary of Safety and Effectiveness:
Line Extension to the Radius® Spinal System

Proprietary Name:	Radius® Spinal System
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	1) Pedicle Screw Spinal System, 21 CFR §888.3070 2) Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 3) Spinal Intervertebral Body Fixation Orthosis 21 CFR §888.3060
Proposed Regulatory Class:	Class III
Device Product Code:	NKB, KWP, KWQ, MNH, MNI
For Information contact:	Curtis Truesdale Regulatory Affairs Project Manager 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8296 Fax: (201) 760-8496 Email: Curtis.Truesdale@Stryker.com
Date Summary Prepared:	July 7, 2010
Predicate Devices	▪ Stryker Spine Radius® Spinal System, K070631, K062270, K082608 ▪ Medtronic CD Horizon (Legacy) Spinal System, K020709 ▪ DePuy Spine Moss Miami System, K950697
Description of Device Modification	This 510(k) is intended to introduce an extension to the existing Radius® Spinal System. The proposed line extension includes the additional screws, rods, and cross connectors.

Intended Use

The Radius® Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the Radius® Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patient 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 Radius® Spinal System can also be linked to the Xia® Titanium Spinal System via the Ø5.5 mm to Ø6.0 mm Radius® rod-to-rod connector.

Summary of the Technological Characteristics

Documentation is provided which demonstrates the new components of the Stryker Spine Radius® Spinal System to be substantially equivalent to the predicate devices in terms of material, design, mechanical performance and indications for use. Static Compression Bending testing, Static Torsion testing and Fatigue Compression Bending testing per ASTM F1717 were conducted on the Radius Spinal System 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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUL - 8 2010

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

Re: K101144
Trade/Device Name: Radius® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP, KWQ
Dated: June 09, 2010
Received: June 10, 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,

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

510(k) Number (if known): K101144

Device Name: Radius® Spinal System Line Extension – additional screws, rods & connectors.

Indications for Use:

The Radius® Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the Radius® Spinal System is 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 Radius® Spinal System can also be linked to the Xia® Titanium Spinal System via the Ø5.5 mm to Ø6.0 mm Radius® rod-to-rod connector.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K101144