

Line Extension to the Radius™ Spinal System

Special 510(k) Premarket Notification

**510(k) Summary**  
**Line Extension to the Radius™ Spinal System**

7/13/07

Proprietary Name: Radius™ Spinal System

Common Name: Spinal Fixation Appliances

Proposed Regulatory Class: Class III and Class II

Orthosis, Spinal Pedicle Fixation, For Degenerative  
Disc Disease  
21 CFR 888.3070Spinal intervertebral body fixation orthosis  
21 CFR 888.3060Spinal interlaminar fixation orthosis  
21 CFR 888.3050

Device Product Code: NKB, KWP, KWQ, MNH, MNI

For Information contact: **Simona Voic**  
**Regulatory Affairs Project Manager**  
**2 Pearl Court**  
**Allendale, NJ 07401**  
**Telephone: (201) 760-8145**  
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Date Summary Prepared: July 10, 2007

## Line Extension to the Radius™ Spinal System

## Special 510(k) Premarket Notification

## Predicate Devices

- Stryker Spine Radius™ Spinal System, K062270
- Stryker Spine Xia® Spinal System, K043473, K012870, K031893, K052181, K060631.
- Medtronic Sofamor Danek CD Horizon® Legacy™ System, K020709.

## Description of Device Modification

This 510(k) is intended to introduce an extension to the existing Radius™ Spinal System. The proposed line extension includes additional staples, and 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 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

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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, and indications for use. Engineering analysis and testing to demonstrate compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 was completed for the Stryker Spine Radius™ Spinal System, including the subject components.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 13 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Stryker Spine  
% Ms. Simona Voic  
Regulatory Affairs Project Manager  
2 Pearl Court  
Allendale, NJ 07401

Re: K070631  
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 14, 2007  
Received: June 15, 2007

Dear Ms. Voic:

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.

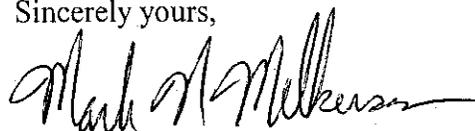
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Ms. Simona Voic

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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  
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): K070631

Device Name: Line Extension to the Radius™ Spinal System

Indications for Use:

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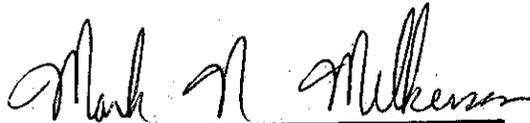
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

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           K070631