Special 510(k): Device Modification
Summary of Safety and Effectiveness for
Xia® Stainless Steel Long Arm Screws

DEC 1 1 2006

Proprietary Name:	Xia® Stainless Steel Spinal System
Common Name:	Spinal Fixation Appliances
Proposed Regulatory Class:	Class III Spinal Interlaminal Fixation Orthosis, 21 CFR 888.3050 Spinal Intervertebral Body Fixation Orthosis, 21 CFR 888.3060 Pedicle Screw Spinal System 21 CFR 888.3070(b)(1) and (b)(2)
Device Product Code:	NKB, MNH, MNI, KWP, KWQ
For Information contact:	Simona Voic Regulatory Affairs Project Manager 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8145 Fax: (201) 760-8345 Email: Simona.Voic@stryker.com
Date Summary Prepared:	November 9, 2006
Predicate Devices	Stryker Spine: • Xia® Spinal System: K061854, K012870, K031090 • Osteonics Spinal System, K951725

Description of Device Modification	This 510(k) is intended to introduce a new Stainless Steel material grade for the previously cleared Xia long arm Monoaxial and Polyaxial screws (K061854).
Intended Use	The Xia® Stainless Steel Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation 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; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.
Summary of the Technological Characteristics	Documentation is provided which demonstrates the new long arm screws of the Stryker Spine Xia® Stainless Steel Spinal System to be substantially equivalent to its predicate devices in terms of its 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 Xia® Stainless Steel modified long arm screws.

Class III Summary

A Class III Summary has been submitted in predicate 510(k) #K060361 for the entire Stryker Xia® Spinal System line, including the Xia® Stainless Steel Spinal System. The Class III summary submitted in 510(k) #K060361 also applied to the Xia® long arm titanium alloy and stainless steel screws and hooks cleared via K061854.

The Class III summary, incorporated into the current Special 510(k) by reference, reviewed information relevant to the types of safety and effectiveness problems reported for pedicle screw/rod systems when used for the Class III indications of degenerative disc disease and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment).

The conclusion of the Class III Summary was that current literature and MAUDE experience reports suggest that the types of safety and effectiveness problems associated with pedicle screw and rod systems are well known and include: device-related events such as screw breakage, component disassembly, pedicle fracture, component migration/loosening/fracture, and infection; and procedure-related events such as intraoperative assembly difficulty, and events associated with any major surgical procedure (such as myocardial infarction, deep vein thrombosis, and urinary tract infection). Complications can lead to revision surgery, and are sometimes associated with neural injury. Further, surgery does not always achieve its goals of stability and pain relief, and patients can develop instability or pain at adjacent spinal segments. The information presented in this summary does not suggest that the Class III use of pedicle screw/rod systems as described in 21 CFR 888.3070 is associated with any different types of safety and effectiveness problems than are seen with the Class II uses of the same pedicle screw/rod systems.

The device modification of the previously cleared Xia® Stainless Steel long arm screws (K061854), to change from one grade of implantable Stainless Steel to another, raises no new types of safety or effectiveness problems, as the devices have been demonstrated through a comparison of design features, materials, intended use, and performance characteristics, to be substantially equivalent to existing Xia® Stainless Steel Spinal System screw and hook components.

CLASS III CERTIFICATION

Certification of Adverse Safety and Effectiveness Information
Pursuant to 513(f) of the Federal Food, Drug and Cosmetic Act

I certify that, in my capacity as Senior Director of Regulatory and Clinical Affairs of Stryker Spine I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety and effectiveness problems that have been reported for pedicle screws. I further certify that I am aware of the types of problems to which pedicle screws are susceptible and that, to the best of my knowledge, the summary of the types and causes of safety and/or effectiveness problems about pedicle screws reported in K060361 are complete and accurate.

Susan Krasny

Susan Krasny, RAC, Ph.D.
Senior Director, Regulatory and Clinical Affairs

Date: 2 Nov 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

DEC 1 1 2006

Re: K063428
Trade/Device Name: Xia® Stainless Steel Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, KWP, KWQ, MNI, MNH
Dated: November 9, 2006
Received: November 13, 2006

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.

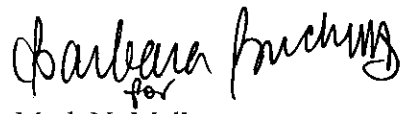
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative,
and Neurologic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063428

Device Name: Xia® Stainless Steel Spinal System

Indications for Use:

The Xia® Stainless Steel Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation 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; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

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)

Barbara Buchman for MAM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063428