MAR 2 - 2005

510(k) Summary of Safety and Effectiveness: Stryker Spine TRIO® PS

Proprietary Name:	Stryker Spine TRIO® PS
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	Pedicle Screw Spinal System, 21 CFR 888.3070
Proposed Regulatory Class:	Class II
Device Product Code:	87 MNH: Orthosis, Spondyloisthesis Spinal Fixation 87 MNI: Orthosis, Spinal, Pedicle Fixation
For Information contact:	Simona Voic 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8145 Fax: (201) 760-8345 Email: Simona.Voic@stryker.com
Date Summary Prepared:	January 12, 2005

Device Description

The Stryker Spine TRIO® PS is comprised of spinal screws, plates and locking components. The components are available in a variety of sizes in order to accommodate patient anatomy and are fabricated from titanium alloy. The components of the TRIO® PS System will be provided non-sterile.

Predicate Devices:

Xia Spinal System, Howmedica Osteonics Corporation [K013823]
Osteonics® Spinal System, Osteonics Corporation [K951725]

Intended Use

The Stryker Spine TRIO® PS is a posterior, noncervical (T10-S1), pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients:

As an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the spine: severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis) tumor, pseudoarthrosis, and previous failed fusion.

The Stryker Spine TRIO® PS is also a sacral screw fixation system indicated for 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, deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudoarthrosis and previous failed fusion.

Summary of the Technological Characteristics:

Documentation was provided which demonstrates the Stryker Spine TRIO® PS to be substantially equivalent to its predicate devices in terms of its material, design, and indications for use. Testing to demonstrate compliance with FDA's Guidance "Spinal System 510(k)s", May 3, 2004 was completed for the Stryker Spine TRIO® PS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 - 2005

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

Re: K043180
Trade/Device Name: Stryker Spine TRIO® Plate System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: II
Product Code: MNH and MNI
Dated: January 14, 2005
Received: January 18, 2005

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.

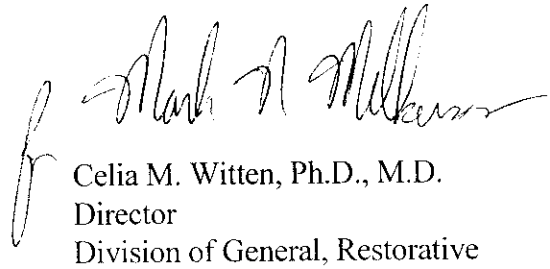
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 se 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
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): K043180

Device Name: Stryker Spine TRIO® PS

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

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

510(k) Number K043180