K040261

Special 510(k) Summary of Safety and Effectiveness: Line extension to the Reflex™ Anterior Cervical Plate System

Proprietary Name:	Reflex™ Hybrid Anterior Cervical Plate System
Common Name:	Anterior Cervical Plate System
Proposed Regulatory Class:	Class II
Classification Name and Reference:	Spinal Invertebral Body Fixation Orthosis 21 CFR §888.3060
Device Product Code:	87 KWQ: Appliance, Fixation, Spinal Intervertebral Body
For Information contact:	Simona Voic Regulatory Affairs Project Manager Stryker Spine 6 Pearl Court Allendale, NJ 07401-1677 Telephone: (201) 760-8145 Fax: (201) 760-8345 Email: Simona.Voic@stryker.com
Date Summary Prepared:	January 27, 2004

Predicate Device Information:

Stryker Spine's Reflex™ Anterior Cervical Plate System consists of bone plates and screws. Both components are available in a variety of lengths in order to accommodate patient physiology. The components are fabricated from titanium alloy per ASTM F-136, ISO 5832-3 and ASTM F-1813. The implants are provided non-sterile.

Description of Device Modification

This submission is intended to expand the Reflex™ ACP System product line by adding the Reflex™ Hybrid ACP System, a low profile anterior cervical plate system, intended for unilateral fixation. Similar to its predicate device, the Reflex™ Hybrid ACP System consists of bone plates and screws, available in a variety of lengths. The components of the subject device are fabricated from Titanium alloy as described in ASTM F-136 and ISO 5832-3. The Reflex™ Hybrid ACP System will be provided non-sterile.

Intended Use:

The Reflex™ ACP System and Reflex™ Hybrid ACP System are intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1.

Indication for Use:

The Reflex™ ACP System and Reflex™ Hybrid ACP System are indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications: Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), trauma (including fractures), tumors, deformities or curvatures (including kyphosis, lordosis or scoliosis), pseudoarthrosis, failed previous fusion, decompression of the spinal cord following total or partial cervical vertebrectomy, spondylolisthesis and spinal stenosis.

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WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Statement of Technological Comparison:

Equivalency of the Reflex™ Hybrid ACP System is based on similarities in intended use, indications for use, materials, and design to the predicate device. Testing has been conducted demonstrating substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 6 2004

Mr. Christopher McDonnell
Vice President Global Technology
Stryker Spine
6 Pearl Court
Allendale, NJ 07401-1677

Re: K040261
Trade/Device Name: Reflex™ Hybrid Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 3, 2004
Received: February 4, 2004

Dear Mr. McDonnell:

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.

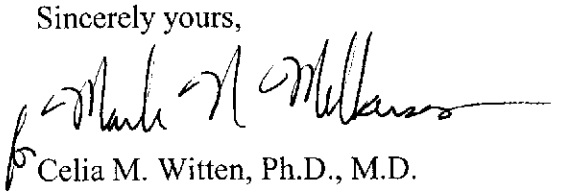
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/dsma/dsmamain.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): K040261

Device Name: Reflex™ Hybrid Anterior Cervical Plate (ACP) System

Indications For Use:

The Reflex™ Hybrid ACP System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis or scoliosis)
- Pseudoarthrosis
- Failed previous fusion
- Decompression of the spinal cord following total or partial cervical vertebrectomy.
- Spondylolisthesis
- Spinal Stenosis

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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

for Mark N. Melkerson

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

510(k) Number K040261