Special 510(k) Summary of Safety and Effectiveness: Line Extension to the Stryker Spine Reflex™ Hybrid ACP System

Proprietary Name:	Reflex™ Hybrid ACP System
Common Name:	Anterior Cervical Plate System
Proposed Regulatory Class:	Class II
	Spinal Intervertebral Body Fixation Orthosis, 21 CFR 888.3060
Device Product Code:	KWQ
Sponsor:	Stryker Spine
For Information contact:	Simona Voic Regulatory Affairs Project Manager Stryker Spine 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8145 Fax: (201) 760-8345 Email: Simona.Voic@stryker.com
Date Summary Prepared:	August 7, 2006
Predicate Device	Reflex™ Hybrid ACP System (K040261) Synthes Cervical Spine Locking Plate System (K000536 and K000742)

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Intended 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 thefollowing 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
Device Description	The Reflex™ Hybrid ACP System includes plates (1-level, 2-level, 3-level, and 4-level), 4.0 mm and 4.5mm diameter bone screws (variable angle self-drilling, variable angle self-tapping, fixed angle self-drilling, and fixed-angle self-tapping), and a locking ring component. This submission adds three new 4-level plate lengths to the Reflex™ Hybrid ACP System.

Summary of the Technological Characteristics	The intended use and materials of the subject devices are identical to those of the predicate device system. Engineering analysis demonstrated that the subject device system is substantially equivalent in terms of performance characteristics to the predicate device system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2006

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

Re: K062310
Trade/Device Name: Stryker Spine™ Reflex Hybrid ACP System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 07, 2006
Received: August 8, 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, and 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 Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K062310

Device Name: Stryker Spine Reflex™ Hybrid 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____ (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 K062310