510(k) Summary for Stryker Spine Oasys Bone Screw

Proprietary Name:	Stryker Spine Oasys Bone Screw
Common Name:	Transfacetpedicular Screw Fixation System
Proposed Regulatory Class:	Unclassified
Device Product Code:	87 MRW: System, Facet Screw Spinal Device
For Information contact:	Karen Ariemma Regulatory Affairs Specialist Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Telephone: (201) 831-5718 Fax: (201) 831-6038 Email: kariemma@howost.com
Date Summary Prepared:	May 27, 2003

Device Description

The Stryker Spine Oasys Bone Screw is available in 3.5 and 4.0 mm diameters and a variety of lengths in order to accommodate patient anatomy. The components are fabricated from titanium alloy. The implants will be provided non-sterile.

Indications for Use

The Stryker Spine Oasys Bone Screw is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. The Stryker Spine Oasys Bone Screw is indicated for bilateral fixation, with or without bone graft, at single or multiple levels, from C2 to T3. The Stryker Spine Oasys Bone Screw is indicated for treating any or all of the following:

- Trauma, including fractures and/or dislocations
- Spondylolisthesis
- Spondylolysis
- Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity

- Degenerative disc disease (DDD) as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Degenerative disease of the facets with instability

Substantial Equivalence

Equivalency of this device is based on similarities in intended use, materials, and design to other currently marketed transfacetpedicular screws. Mechanical testing demonstrated comparable mechanical properties to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2003

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K031657
Trade Name: Stryker Spine Oasys Bone Screw
Regulatory Class: Unclassified
Product Code: MRW
Dated: May 27, 2003
Received: May 28, 2003

Dear Ms. Ariemma:

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" (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/dsma/dsmamain.html.

Sincerely yours,

for 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

510(k) Number (if known): K031657

Device Name: Stryker Spine Oasys Bone Screw

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use____(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Melkerson

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

510(k) Number K031657