DEC 18 1998

K984302

510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® Spinal System Cylindrical Bone Screws

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Osteonics Corporation 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Kate Sutton Regulatory Affairs Specialist
Date of Summary Preparation:	November 30, 1998

Device Identification

Proprietary Name:	Osteonics® Spinal System Cylindrical Bone Screws
Common Name:	Spinal fixation appliance
Classification Name and Reference:	Spinal Interlaminal Fixation Orthosis 21 CFR §888.3050

Predicate Device Identification

The Osteonics® Spinal System, which includes bone screws, was determined to be substantially equivalent via 510(k) #K951725. The proposed cylindrical bone screws of the Osteonics® Spinal System are substantially equivalent to the tapered bone screws in the Osteonics® Spinal System.

Device Description

The Osteonics® Spinal System is comprised of single-use, non-sterile devices manufactured from ASTM F-136-96 Titanium Alloy (Ti6Al-4V ELI). The Osteonics® Spinal System bone screws are top loading screws that are threaded distally, have a forked proximal design, and are available in both standard and extended ("extra-long" or "long arm") proximal length configurations. The cylindrical bone screws will be available in standard and extra-long versions in lengths and diameters identical to the predicate top loading tapered screws.

Intended Use:

The following are specific indications for the Osteonics® Spinal System:

For non-pedicular fixation of the T4-S2 spine:

- Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis)
- Vertebral fracture or dislocation
- Spinal stenosis
- Spondylolisthesis
- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).
- Previously failed fusion
- Spinal tumor

For pedicular use:

- Additionally, when used as a pedicle screw system, the system is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. Pedicle screws are not intended for placement in pedicles above L3.

Statement of Technological Comparison:

The substantial equivalence of the Osteonics® Spinal System cylindrical bone screws to the predicate bone screws in the Osteonics® Spinal System, in terms of intended use and design features, is based on the following:

Intended Uses:

The intended uses of the subject bone screws are identical to those of the predicate bone screws.

Material:

The Osteonics® Spinal System is manufactured from ASTM F-136-96 titanium alloy (Ti6Al-4V ELI).

Design:

The design of the modified cylindrical bone screw differs from the predicate bone screw in that the modified bone screw distal diameter is the same as the proximal diameter. The function of the modified spinal system bone screws remains unchanged and is identical to that of the predicate Danek TSRH bone screws.

Summary

Based on the similarities presented above and the supporting analyses, the substantial equivalence of the subject cylindrical bone screws to the predicate tapered bone screws of the legally marketed Osteonics® Spinal System is demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 1998

Ms. Kate Sutton
Regulatory Affairs Specialist
Stryker Osteonics®
59 Route 17
Allendale, New Jersey 07401-1677

Re: K984302
Cylindrical Bone Screws - part of the Osteonics® Spinal System
Regulatory Class: II
Product Codes: MNH and KWP
Dated: November 30, 1998
Received: December 2, 1998

Dear Ms. Sutton:

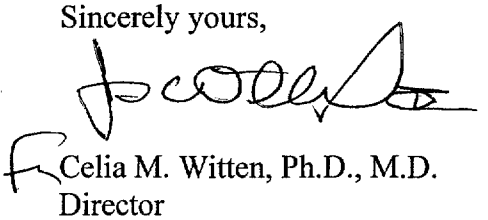
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K984302

Device Name: Osteonics® Spinal System

Indications For Use:

The uses for the legally marketed Osteonics® Spinal System are as follows:

Non-Pedicular Use; fixation of the T4-S2 spine:

- Long and short curve scoliosis
- Vertebral fracture or dislocation
- Spondylolisthesis
- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Previously failed fusion
- Spinal tumor

Pedicular Use:

- When used as a pedicle screw system, the system is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. Pedicle screws are not intended for placement in pedicles above L3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984302

Prescription Use X OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)