4/30/99

K984375

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
OSTEONICS® SPINAL SYSTEM - SACRAL OFFSET CONNECTOR ASSEMBLY

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677
201-825-4900

Contact Person:

Marybeth Naughton
Regulatory Affairs Team Member

Date Summary Prepared:

December 4, 1998

Device Identification

Proprietary Name:

Osteonics® Spinal System -Sacral Offset Connector Assembly

Common Name:

Spinal Fixation Appliances

Classification Name and Reference:

Spinal Interlaminal Fixation Orthosis
21 CFR §888.3050
Pedicle Screw System
21 CFR §888.0370

Predicate Device Identification

The Osteonics® Spinal System Sacral Offset Connector Assembly components are substantially equivalent to other legally marketed spinal system sacral offset components. These predicate components are part of the commercially available spinal systems stated below:

- Tacoma™ Sacral Plate System: Sofamor Danek
- Saddle with Anchor™ Fixation System: Advanced Spine Fixation Systems, Inc.

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 Sacral Offset Connector Assembly may be used in any application where supplemental sacral screw placement is desired by the surgeon. This assembly allows a sacral connector with supplemental sacral screw to the joined to the spinal rod in the sacrum. The sacral offset blocker secures the sacral screw to the connector assembly. The Clamping Screw is used with the Sacral Offset Connector to provide a stable lock on the longitudinal spinal rod.

Intended Use

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

As a non-pedicle screw system of the T4-S2 spine, the Osteonics® Spinal System is indicated for:

- 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 fixation system of the non-cervical posterior spine in skeletally mature patients, the Osteonics Spinal System is indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

- In addition, the Osteonics Spinal system is indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint, having fusions with autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below)with removal of the implants after the development of a solid fusion mass.

Statement of Technological Comparison

The components of the Osteonics® Spinal System Sacral Offset Connector Assembly share the same materials, intended uses and basic design concepts as that of the predicate devices. Fatigue and static testing demonstrates the mechanical and endurance properties of these components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1999

Ms. Marybeth Naughton
Regulatory Affairs Team Member
Stryker Osteonics
59 Route 17
Allendale, New Jersey 07401-1677

Re: K984375
Trade Name: Osteonics® Spinal System Sacral Offset Connector Assembly
Regulatory Class: II
Product Codes: KWP, MNH and MNI
Dated: February 24, 1999
Received: February 25, 1999

Dear Ms. Naughton:

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 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 requirement, 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" (21 CFR 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for 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): K984375

Device Name: Osteonics® Spinal System

Indications For Use:

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

As a posterior, non-pedicle screw system of the T4-S2 spine, the Osteonics® Spinal System is indicated for:

- 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 fixation system of the non-cervical posterior spine in skeletally mature patients, the Osteonics Spinal System is indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

- In addition, the Osteonics Spinal system is indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint, having fusions with autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below)with removal of the implants after the development of a solid fusion mass.

(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 K984375

Prescription Use X OR Over-The-Counter Use ____

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