

K983152

510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® Spinal System 5.5mm & 10.0mm 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:

August 31, 1998

Device Identification

Proprietary Name:

Osteonics® Spinal System 5.5mm &
10.0mm Bone Screws

Common Name:

Spinal fixation appliance

Classification Name and Reference:

Spinal Interlaminar 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 5.5mm and 10.0mm bone screws of the Osteonics® Spinal System are substantially equivalent to those bone screws in the Osteonics® Spinal System and the 5.5mm bone screws of the following competitive devices, which have previously been determined substantially equivalent by FDA:

- Danek TSRH Spinal System
- AcroMed Titanium Bone Screws

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 5.5mm bone screws will be available in standard and extra-long versions in lengths of 30mm, 35mm, 40mm, and 45mm. The 10.0mm bone screws will be available in one standard version only in lengths from 35mm to 60mm in increments of 5mm.

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 5.5mm and 10.0mm bone screws to the predicate bone screws in the Osteonics® Spinal System, and for the 5.5mm bone screws, the Danek TSRH Spinal System and AcroMed Titanium Bone Screws, in terms of intended use and design features, is based on the following:

Intended Uses:

The intended uses of the subject devices are substantially equivalent to those of the predicate devices.

Material:

The Osteonics® Spinal System and the AcroMed Titanium Bone Screws are manufactured from ASTM F-136-96 titanium alloy (Ti6Al-4V ELI). The Danek TSRH Spinal System is manufactured from ASTM F-138-92 Stainless Steel alloy.

Design:

The design and function of the subject spinal system bone screws remains unchanged and is substantially equivalent to that of the predicate bone screws.

Summary

Based on the similarities presented above and the supporting testing summary, the substantial equivalence of the Osteonics® Spinal System to the bone screws of the legally marketed Osteonics® Spinal System, Danek TSHR Spinal System, and AcroMed Titanium Bone Screws is demonstrated.



SEP 25 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kate Sutton
Regulatory Affairs Specialist
OSTEONICS Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K983152
5.5mm and 10.0mm Bone Screws to be used with the
Osteonics® Spinal System
Regulatory Class: II
Product Codes: MNH and KWP
Dated: September 1, 1998
Received: September 9, 1998

Dear Ms. Sutton:

We have reviewed your Section 510(k) notification of intent to market the device system referenced above and we have determined the device system is substantially equivalent (for the indications for use stated in the enclosure) to device systems marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal, Food, Drug, and Cosmetic Act (Act). This decision is based on your device system being found equivalent only to similar device systems labeled and intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral 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. You may, therefore, market your device system subject to the general controls provisions of the Act and the limitations identified below.

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. Note that labeling or otherwise promoting this device system for pedicular screw fixation/attachment for indications other than severe spondylolisthesis, as described above, would cause the device system to be adulterated under 501(f)(1) of the Act.

This device system, when intended for pedicular screw fixation/attachment to the spine for indications other than severe spondylolisthesis, as described above, is a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. All labeling for this device, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system using pedicle screws is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral 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.
2. You may not label or in anyway promote this device system for pedicular, screw fixation/attachment to the cervical, thoracic or lumbar vertebral column for intended uses other than severe spondylolisthesis, as described above. The package insert must include the following statements:

WARNINGS:

- When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral (L5-S1) vertebral joint.
- The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 vertebral joint.
- Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
- Potential risks identified with the use of this device system, which may require additional surgery, include:

device component fracture,
loss of fixation,
non-union,
fracture of the vertebra,
neurological injury, and
vascular or visceral injury.

See Warnings, Precautions, and Potential Adverse Events sections of the package insert for a complete list of potential risks.

3. Any pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described by item 1, for this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described above, must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.
4. Any previous warning statements identified as part of previous 510(k) clearances or required by OC/Labeling and Promotion which stated that a component/system was not approved for screw fixation into the pedicles of the spine must be replaced by the warnings of items 1 and 2 above.

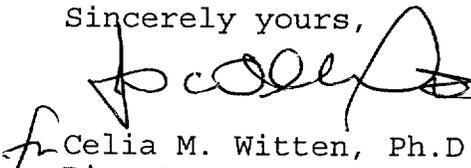
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

FDA advises that the use of your device system with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or those of other manufacturers, may also be required.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,


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): K983152

Device Name: Osteonics® Spinal System 5.5mm & 10.0mm Bone Screws

Indications For Use:

The uses for the Osteonics® Spinal System 5.5mm & 10.0mm Bone Screws, as part of the legally marketed Osteonics® Spinal System, are as follows:

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

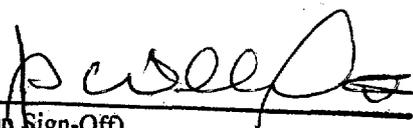
- Long and short curve scoliosis
- Vertebral fracture or dislocation
- Spondylolisthesis
- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Previously failed fusion
- Spinal tumor

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 K983152

Prescription Use X

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)