

Osteonics® Long Arm Containment Ring

K981452

510(k) Premarket Notification

MAY 20 1998

**510(k) Premarket Notification  
Summary of Safety and Effectiveness  
for the  
Osteonics® Long Arm Containment Ring**

**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:

May 5, 1998

**Device Identification**

Proprietary Name:

Osteonics® Long Arm  
Containment Ring (a component of  
the Osteonics® Spinal System)

Common Name:

Spinal fixation appliance

Classification Name and Reference:

Spinal Interlaminar Fixation Orthosis  
21 CFR §888.3050

**Predicate Device Identification**

The Osteonics® Long Arm Containment Ring is substantially equivalent to the following competitive and/or Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Osteonics® Spinal System Low Profile Cap

**Device Description**

The Osteonics® Long Arm Containment Ring is placed over the long arms of the screw to aid the physician in achieving a clean break along the scored sections of the screw arms. Additionally, placement of the Osteonics® Long Arm Containment Ring over the body of the screw protects soft tissues and prevents the arms of the screw from spreading as the screw blocker is tightened. The locking mechanism of the containment ring is identical to that of the Osteonics® Spinal System Low Profile Cap. The containment ring does not replace the Low Profile Cap; rather, it offers surgeons an alternative to the Low Profile Cap, if so desired.

**Intended Use:**

The containment rings are for use with screws which are indicated for sacral fixation, or for limited pedicular fixation. When used as a pedicle screw system, the system is intended only for use with autogenous bone graft in order to facilitate fusions of the L5-S1 joint in patients with grade 3 or 4 spondylolisthesis. Screws are not intended for placement in the pedicles above L3, and are intended for removal after development of a solid fusion mass.

The specific indications for the Osteonics® Long Arm Containment Ring, as a component of the legally marketed Osteonics® Spinal System, fall within the same indications as all components of the Osteonics® Spinal System:

**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.

**Statement of Technological Comparison:**

The substantial equivalence of the Osteonics® Long Arm Containment Ring to the predicate Osteonics® Spinal System Low Profile Cap—in terms of intended use, material, and design features—is based on the following:

**Intended Uses:**

The intended uses of the subject Osteonics® Long Arm Containment Ring are identical to those of the predicate device.

**Material:**

Both subject and predicate devices use the identical material, ASTM F-136-96 Titanium Alloy (Ti6Al-4V ELI).

**Design:**

The design and function of the Osteonics® Long Arm Containment Ring is consistent with that of the predicate Osteonics® Spinal System Low Profile Cap and differs only in the following:

Osteonics® Long Arm Containment Ring§10(k) Premarket Notification

- The diameter of the hole that provides access to the screw blocker has been increased.
- The external diameter of the subject device is 1 mm larger than that of the predicate device (15 mm vs. 14 mm).

None of these design differences raise any new questions of safety or effectiveness.

Summary

Based on the similarities presented above, the supporting testing summary, the pre-clinical data incorporated by reference to a prior submission, and the fact that the Osteonics® Long Arm Containment Ring employs standard sterilization and packaging methods, the substantial equivalence of the Osteonics® Long Arm Containment Ring to the legally marketed Osteonics® Spinal System Low Profile Cap is demonstrated.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 20 1998

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

Re: K981452  
Long Arm Containment Ring - part of the Osteonics®  
Spinal System  
Regulatory Class: II  
Product Codes: KWP and MNH  
Dated: April 20, 1998  
Received: April 22, 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.

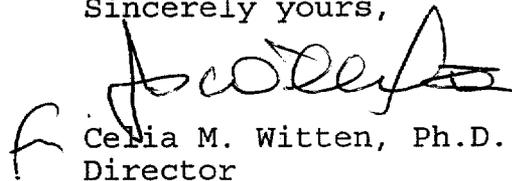
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 (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): K981452

Device Name: Osteonics® Long Arm Containment Ring

Indications For Use:

The uses for the Osteonics® Long Arm Containment Ring, 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
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**  
**Division of General Restorative Devices**  
**510(k) Number** K981452

Prescription Use X  
(Per 21 CFR 801.109)