

Osteonics® Combination Ring/Blocker K990158 510(k) Premarket Notification

FEB 1 1999

**510(k) Premarket Notification  
Summary of Safety and Effectiveness  
for the  
Osteonics® Combination Screw Ring/Blocker  
(A Component of the Osteonics® Spinal System)**

**Submission Information**

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Marybeth Naughton Regulatory Affairs Team Member
Date of Summary Preparation:	January 20, 1999

**Device Identification**

Proprietary Name:	Osteonics® Combination Screw Ring/Blocker
Common Name:	Spinal fixation appliance
Classification Name and Reference:	Spinal Interlaminar Fixation Orthosis 21 CFR §888.3050 Pedicle Screw System 21 CFR §888.3070

**Predicate Device Identification**

The Osteonics® Long Arm Containment Ring, a component of the Osteonics® Spinal System, was determined to be substantially equivalent via 5109k) #K981452. The Osteonics® Spinal System Screw Blocker was determined to be substantially equivalent via 5109k) #K951725. The proposed Osteonics® Combination Screw Ring/Blocker is substantially equivalent to the Osteonics® Long Arm Containment Ring and Osteonics® Spinal System Screw Blocker.

**Device Description**

The Combination Screw Ring/Blocker incorporates the blocker into the design of the containment ring, resulting in a single, preassembled component. The blocker portion of the Combination Screw Ring/Blocker is preassembled in the factory to the containment ring via a snap-fit assembly process. The proximal portion of the existing Screw Blocker has been modified to include a proximal circular "lip". Two bars on the proximal side of the containment ring expand and retract to allow the snap-fit insertion of the proximal lip of the blocker component.

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The locking mechanism and function of the Combination Screw Ring/Blocker is identical to that currently employed by the Long Arm Containment Ring and the Screw Blocker. The Combination Screw Ring/Blocker is placed over the screw arms. The blocker is then tightened, which expands the proximal portion of the screw creating a friction-fit lock between the proximal screw and the containment ring portion of the Combination Screw Ring/Blocker. The screw arms are then broken off.

**Intended Use:**

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

**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.

**Statement of Technological Comparison:**

The substantial equivalence of the Osteonics® Combination Screw Ring/Blocker, the predicate Long Arm Containment Ring and Screw Blocker of 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 and predicate devices are identical.

**Material:**

All components of the Osteonics® Spinal System are manufactured from ASTM F-136-96 titanium alloy (Ti6Al-4V ELI).

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Design:

The subject Combination Screw Ring/Blocker incorporates the blocker into the design of the containment ring, resulting in a single, preassembled component. The blocker portion of the Combination Screw Ring/Blocker is preassembled in the factory to the containment ring via a snap-fit assembly process. The proximal portion of the predicate Screw Blocker has been modified to include a proximal circular "lip". Two parallel bars have been added to the proximal side of the predicate Long Arm Containment Ring. The bars expand and retract to allow the snap-fit insertion of the proximal lip of the blocker component. The function of the Combination Screw Ring/Blocker is identical to that of the predicate Long Arm Containment Ring and Screw Blocker when used together.

Summary

Based on the similarities presented above and the supporting analyses, the substantial equivalence of the subject Combination Screw Ring/Blocker to the predicate Long Arm Containment Ring and Screw Blocker of the legally marketed Osteonics® Spinal System is demonstrated.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K990158  
Osteonics® Spinal System – Combination Screw Ring/Blocker  
Regulatory Class: II  
Product Codes: MNI, MNH, and KWP  
Dated: January 12, 1999  
Received: January 19, 1999

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.

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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,

*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): K990158

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)

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

*Steph R. Wells for CMU*  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of General Restorative Devices  
 510(k) Number K990158

Prescription Use X

OR

Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)

(Optional Format 1-2-96)