DEC 20 1999

K993402

510(k) - Premarket Notification
Summary of Safety and Effectiveness for the
Opus™ 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:

Mary-Catherine Dillon
Regulatory Affairs Specialist

Date of Summary Preparation:

September 30, 1999

Device Identification

Proprietary Name: Opus™ Spinal System

Common Name: Spinal Fixation Appliance

Classification Name and Reference: Spinal Interlaminal Fixation Orthosis
21 CFR §888.3050

Predicate Device Identification

The features of the Opus™ Spinal System are substantially equivalent to features of the following Howmedica Osteonics predicate device, which has been cleared for marketing via the 510(k) process (K951725):

- Osteonics® Spinal System

Device Description

The Opus™ Spinal System is a spinal fixation device for the noncervical spine. All components are manufactured from ISO 5832/3 (equivalent to ASTM F-136-96) titanium alloy (Ti6Al-4V ELI). The system consists of conical and cylindrical screws, rods, lateral connectors, and plates.

Bone Screws: These screws are threaded at both the distal and the proximal ends. The distal aspect of the screws features cancellous bone threads. The proximal aspect of the screws features standard metric threads. The area between the proximal and distal threads has a hexagonal cross-section used to remove the screw. Screws are available in a variety of diameters and lengths. Additionally, the screws are available in extended proximal length and/or extended hexagonal section configurations.

Rods: The spinal rods are 6mm in diameter and range in length from 40mm to 480mm. A 600mm rod is also available. Rods are assembled to the screws through the use of a lateral connector and a rod nut.

Plates: The plates have 2 or 3 holes and their lengths range from 41mm to 75mm. Plates are assembled to the screws through the use of a washer and a plate nut.

Intended Use:

- When used as a pedicle screw fixation system of the non-cevical posterior spine in skeletally mature patients, the Opus™ 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 Opus™ 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 using 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 Opus™ Spinal System share the same material (titanium alloy (Ti6Al-4V ELI)), intended uses, and basic design concepts as those of the predicate Osteonics® Spinal System. Fatigue and static testing demonstrates the comparable 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

DEC 20 1999

Ms. Mary-Catherine Dillon
Regulatory Affairs Team Member
Howmedica Osteonics
59 Route 17
Allendale, New Jersey 07401-1677

Re: K993402
Trade Name: Opus™ Spinal System
Regulatory Class: II
Product Codes: MNI and MNH
Dated: October 6, 1999
Received: October 8, 1999

Dear Ms. Dillon:

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) 594-4595. 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,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993402

Device Name: Opus™ Spinal System

Indications For Use:

- When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the Opus™ 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 Opus™ 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 using 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.

NRO for

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993402

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____

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