K994347

MAR 15 2000

510(k) - Premarket Notification
Summary of Safety and Effectiveness for the
Centaur™ 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 Team Member
Date of Summary Preparation:	December 21, 1999

Device Identification

Proprietary Name:	Centaur™ 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 Centaur™ Spinal System are substantially equivalent to the features of the following DePuy AcroMed predicate device, which has been cleared for marketing via the 510(k) process (K983583):

- MOSS Miami Spinal System

Device Description

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

Bone Screws: There are two different types of screws in the Centaur™ Spinal System. They are primary and secondary screws. The head of the primary screw receives the connectors and the tightening screws for both the plate and rod systems. The head of the secondary screw is shaped to allow for a 5° angulation in all directions. Both the primary and secondary screws are threaded at

the distal end. The distal aspect of the screws feature cancellous bone threads. Screws are available in two diameters: 5.5mm and 7mm, and in lengths of 25mm through 55mm (in 5mm increments).

Rods: There are two types of spinal rods used in the Centaur™ Spinal System. The first type is 4mm in diameter and the second type is 6mm in diameter. Both types range in length from 60mm to 160mm in 10mm increments. Rods are slipped into the rod connector and ball ring and are tightened down by rod locking screws. The rod connectors have a specific anatomic shape. They can be adapted to both the antero-posterior and craniocaudal shape of the lateral vertebra. A ball ring allows for a +/-15 angulation of the 6mmrod. The posterior aspect of the rod system uses the larger rods, and this is the aspect that has the higher profile when implanted. The anterior aspect of the rod system uses the smaller rods which have the lower profile of the implant.

Plates: There are three types of plates used in the Centaur™ Spinal System. All three are L-shaped. The first type, straight plates, range from 30mm to 90mm in length in 10mm increments The second type, lordotic plates, range from 60mm to 90mm in length in 10mm increments. The third type, kyphotic plates, range in length from 50mm to 90mm in 10mm increments. The plate system is not monoblock, thereby allowing more flexibility and greater opportunity for compression which aids fusion. Plates are assembled to the screws through the use of a plate connector and are locked down by set screws.

Intended Use:

When used as an anterior, thoracic/lumbar screw fixation system, the Centaur™ Spinal System is intended to treat deformities of curvature (i.e. scoliosis, kyphosis and/or lordosis), fracture, tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e.discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Statement of Technological Comparison:

The Centaur™ Spinal System shares the same intended use and basic design concepts as those of the predicate DePuy AcroMed MOSS Miami Spinal System. Fatigue and static testing demonstrates the comparable mechanical and endurance properties of these components.

The components of the Centaur™ Spinal System are manufactured from titanium alloy (Ti6Al-4V ELI). This material has a long and successful history of use in orthopedic implant surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2000

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

Re: K994347
Trade Name: CENTAUR Spinal System
Regulatory Class: II
Product Code: KWQ
Dated: December 21, 1999
Received: December 23, 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 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 control provisions of the Act. The general control 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,

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): K994347

Device Name: Centaur™ Spinal System

Indications For Use:

- When used as an anterior, thoracic/lumbar screw fixation system, the Centaur™ Spinal System is intended to treat deformities of curvature (i.e. scoliosis, kyphosis and/or lordosis), fracture, tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e.discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994347