OCT 22 1999

K993181

SPECIAL 510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
HOWMEDICA OSTEONICS® ACCP SYSTEM - CORTICAL SCREWS

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677
201-825-4900

Contact Person:

Mary-Catherine Dillon
Regulatory Affairs Team Member

Date Summary Prepared:

September 22, 1999

Device Identification

Proprietary Name:

Howmedica Osteonics® Anterior Cervical Compression Plating System - Cortical Screws

Common Name:

Anterior Cervical Compression Plate

Classification Name and Reference:

Spinal Invertebral Body Fixation
21 CFR §888.3060

Predicate Device Identification

The Howmedica Osteonics® ACCP System Cortical Screws are substantially equivalent to the cortical bone screws in the Howmedica Osteonics® ACCP System.

Device Description

The Howmedica Osteonics® ACCP System is an anterior cervical single or multi-level plate that incorporates either a monoblock or modular design, which is measured from end to end. Modular end plate sections are secured to each other using locking screws, and are provided preassembled. The Howmedica Osteonics® ACCP is placed longitudinally on the long axis of the cervical spine and is affixed by cortical bone screws. All Howmedica Osteonics® ACCP System components are manufactured from ASTM F-136-98 (ISO 5832/3) titanium alloy.

Intended Use

The indications for the use of the Howmedica Osteonics® ACCP System are as follows:

- degenerative disc disease (neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).
- decompression of the spinal cord following total or partial cervical vertebrectomy
- trauma (fractures)
- tumors
- pseudarthrosis
- failed previous fusions

Statement of Technological Comparison

The subject Howmedica Osteonics® ACCP System Cortical Screw components are substantially equivalent in design and intended use to the cortical bone screws in the predicate Osteonics® ACCP System. The subject and predicate bone screws are manufactured from ASTM F-136-98 (ISO 5832/3) titanium alloy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1999

Ms. Elizabeth A. Staub
Vice President - Quality Assurance, Regulatory Affairs,
Clinical Reasearch
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K993181
Trade Name: Howmedica Osteonics® ACCP System Cortical Screws
Regulatory Class: II
Product Code: KWQ
Dated: September 20, 1999
Received: September 23, 1999

Dear Ms. Staub:

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 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 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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): K993181

Device Name: Howmedica Osteonics® ACCP System Cortical Screws

Indications For Use:

The indications for the use of the Howmedica Osteonics® ACCP System are as follows:

- degenerative disc disease (neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).
- decompression of the spinal cord following total or partial cervical vertebrectomy
- trauma (fractures)
- tumors
- pseudarthrosis
- failed previous fusions

(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 K993181

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)