3/25/99 ATTACHMENT 10 K982798

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
OSTEONICS® ACCP SYSTEM

Submission Information

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

Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677
201-825-4900

Contact Person:

Kate Sutton
Regulatory Affairs Specialist

Date Summary Prepared:

February 5, 1998

Device Identification

Proprietary Name:

Osteonics® Anterior Cervical Compression Plating System

Common Name:

Anterior Cervical Compression Plate

Classification Name and Reference:

Spinal Invertebral Body Fixation
21 CFR §888.3060

Predicate Device Identification

The subject Osteonics® ACCP System components are substantially equivalent to similar anterior cervical plates offered by Synthes.

Device Description

The Osteonics® ACCP System is an anterior cervical plate that incorporates a one-piece monoblock design, or a two- or three-piece modular design, depending on plate length, which is measured from end to end. Modular end plate sections are secured to each other using locking screws, and are provided preassembled. Optional bone graft screws are also available for insertion through the center screw hole of the modular plate designs. The Osteonics® ACCP is placed logitudinally on the long axis of the cervical spine and is affixed by unicortical bone screws. The Osteonics® ACCP is available in lengths ranging from 24mm to 100mm. A slotted locking screw hole on the proximal and distal end of each preassembled plate allows the surgeon to adjust the plate in order to apply compression to a specific area along the cervical spine, thus optimizing the compressive forces which aid in achieving a successful fusion. Locking screws are firmly tightened after the surgeon has adjusted the plate to the desired level of compression. All Osteonics® ACCP System components are manufactured from ASTM F-136-96 titanium alloy.

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Intended Use

The Osteonics® ACCP System is intended for anterior intervertebral screw fixation of the cervical spine for the following indications:

- 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 Osteonics® ACCP System components are substantially equivalent in design and intended use to the predicate anterior cervical plates offered by Synthes. The subject anterior cervical plate is manufactured from ASTM F-136-96 titanium alloy, and the predicate anterior cervical plate is manufactured from commercially pure titanium (CPTi).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 1999

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

Re: K982798
Trade Name: Osteonics® Anterior Cervical Compression Plating (ACCP) System
Regulatory Class: II
Product Code: KWQ
Dated: February 5, 1999
Received: February 8, 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 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

ATTACHMENT 9

510(k) Number (if known): K 982798

Device Name: Osteonics® ACCP System

Indications For Use:

The indications for use of the Osteonics® ACCP System, in keeping with those of other legally marketed anterior cervical plates, are as follows.

The Osteonics® ACCP System is intended for anterior intervertebral screw fixation of the cervical spine for the following indications:

- 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)

Prescription Use X 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 K9827