JUL 20 1999

K990712

510(k) Premarket Notification
Summary of Safety and Effectiveness
for the Osteonics® Solar™ Shoulder Bipolar 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:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	April 1, 1999

Device Identification

Proprietary Name:	Osteonics® Solar™ Shoulder Bipolar System
Common Name:	Bi-Polar Shoulder Components
Classification Name and Reference:	Shoulder joint metal/polymer Semi-constrained cemented prosthesis 21 CFR §888.3660 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis 21 CFR §888.3690

Predicate Device Identification

The Osteonics® Solar™ Shoulder Bipolar components are substantially equivalent to the following competitive device, which have previously been determined substantially equivalent by FDA:

- Biomet Bi-Angular Bi-Polar Shoulder System

K990712

Device Description

The Osteonics® Solar™ Shoulder Bipolar System consists of an Osteonics® Solar™ Shoulder Bipolar Humeral Head Component, an Osteonics® 22 mm Solar™ Shoulder Bipolar Modular Head and an Osteonics® Solar™ Shoulder Humeral Stem. The humeral stem was determined substantially equivalent via 510(k) K955731. There have been no modifications made to the humeral stem. The bipolar head component consists of three preassembled pieces: a metal shell, UHMWPE insert and locking ring. The component will be sold preassembled. The metallic shell is manufactured from ASTM F75 cobalt chromium alloy. The 22 mm bipolar modular head is manufactured from ASTM 1537 cobalt chromium alloy. The Osteonics® Solar™ cobalt chromium Shoulder Bipolar Components (Bipolar Head Component and 22 mm Bipolar Modular Head) are intended to be used in cementless applications and as a hemi-shoulder system. Used as a hemi-shoulder replacement device, the Osteonics® Solar™ Shoulder, Bipolar Humeral Head Components are intended to articulate directly with the anatomic glenoid.

Intended Use:

Indications:
The indications for the Osteonics® Solar™ Shoulder Bipolar System are:

- Aseptic necrosis of the humeral head
- Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Proximal humeral fracture and/or dislocation
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Pathological conditions or age considerations which indicate a more conservative glenoid procedure and avoidance of the use of bone cement in the glenoid.

Statement of Technological Comparison:

The subject devices (Bipolar Humeral Head and Bipolar Modular Head) are substantially equivalent to the bipolar components (Bi-Polar Shell and Bi-

K990712

Angular/Bi-Polar Modular Heads) of the predicate Biomet Bi-Angular Bi-Polar Shoulder System Components in all material and design aspects, indications, and intended use.

Summary

Based on the information presented above, the substantial equivalence of the Osteonics® Solar™ Shoulder Bipolar Component to other legally marketed, class III bipolar shoulder components is demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 1999

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K990712
Trade Name: Osteonics® Solar™ Shoulder Bipolar System
Regulatory Class: III
Product Code: MJT
Dated: March 3, 1999
Received: March 4, 1999

Dear Ms. Ariemma:

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): K990712

Device Name: Osteonics® Solar™ Shoulder Bipolar System

The subject components of the Osteonics® Solar™ Shoulder Bipolar System are single-use devices which are sold sterile and are intended for use with only the other components of the commercially available Osteonics® Solar™ Shoulder System.

The indications for the use of the Osteonics® Solar™ Shoulder Bipolar System components, in keeping with those of other legally devices are as follows:

Indications:

- Aseptic necrosis of the humeral head
- Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Proximal humeral fracture and/or dislocation
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Pathological conditions or age considerations which indicate a more conservative glenoid procedure and avoidance of the use of bone cement in the glenoid.

(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 K990712