

3/15/99

K990598

**Special 510(k) - Device Modification
Summary of Safety and Effectiveness for the
Osteonics® Solar Shoulder Humeral Bearing Head**

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:

Marybeth Naughton
Regulatory Affairs Team Member

Date of Summary Preparation:

February 23, 1999

Device Identification

Proprietary Name:

Osteonics® Solar Shoulder Humeral
Bearing Head

Common Name:

Shoulder Prosthesis

Classification Name and Reference:

Shoulder joint humeral (hemi-shoulder)
Metallic uncemented prosthesis
21 CFR §888.3690
Or
Shoulder joint metal/polymer semi-
constrained cemented prosthesis
21 CFR §888.3660

Predicate Device Identification

The modified features of the Osteonics® Solar Shoulder Humeral Bearing Heads are substantially equivalent to features of the following Osteonics® predicate devices, which have been cleared for marketing via the 510(k) process:

- Osteonics® Solar Shoulder Humeral Bearing Head (#K955731)

Device Description

The Osteonics® Solar Shoulder Humeral Bearing Heads are currently marketed devices that are being modified. The modification to the device involves a manufacturing process change in

manufacturing of the humeral bearing head from wrought ASTM (American Society for Testing and Materials) F-1537 cobalt chromium alloy to cast ASTM F-75 cobalt chromium alloy. Howmedica Osteonics intends to replace the current line of wrought cobalt chromium alloy humeral bearing heads with the subject cast cobalt chromium alloy humeral bearing heads. Minor dimensional changes will accompany the manufacturing process change. When changing from a machining process to a casting process, certain design features (dimensional) must be added to the cast part that is not necessary to the machined part when being manufactured. The internal geometry of the cast part requires draft angles to be placed on all walls of the device that are parallel to the parting line to facilitate the removal of the part from the casting mold. These angles range from approximately 0.5 degrees to 1.5 degrees per side.

Intended Use:

The intended use of the modified humeral bearing heads is identical to that of the unmodified humeral bearing heads. As with the predicate humeral bearing heads, the modified humeral bearing heads are single use devices. They are intended for mating with the Osteonics® Solar Humeral Stems. The Osteonics® Solar Humeral Components are designed to be used in either cemented or cementless applications, as either a hemi-shoulder or a total shoulder component. For use as a total shoulder replacement, the modified and predicate humeral bearing heads may be used in conjunction with any legally marketed Osteonics glenoid component. The indications for the Osteonics® Solar Shoulder Components include:

- 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.
- Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Performance Data:

Engineering Analyses have been performed to demonstrate that mechanical properties of the cast cobalt chromium alloy to be well within the acceptable limits for the subject device.

Statement of Technological Comparison:

All features of the Osteonics® Solar Shoulder Humeral Bearing Head are unchanged with the exception of 1) the change in materials from wrought ASTM F-1537 cobalt chromium alloy to cast ASTM F-75 cobalt chromium alloy and 2) minor dimensional changes required for the casting procedure.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 1999

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

Re: K990598
Osteonics® Solar Shoulder Humeral Bearing Head
Regulatory Class: III
Product Codes: KWS and HSD
Dated: February 23, 1999
Received: February 24, 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.

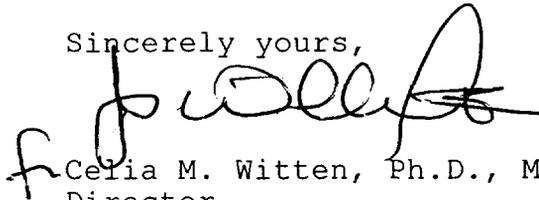
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Elizabeth A. Staub

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,



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): K990598

Device Name: Osteonics® Solar Shoulder Humeral Bearing Head

Indications For Use:

The indications for the use of the Osteonics® Solar Shoulder Humeral Bearing Head , in keeping with those of other legally marketed Osteonics® shoulder components, 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.
- Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

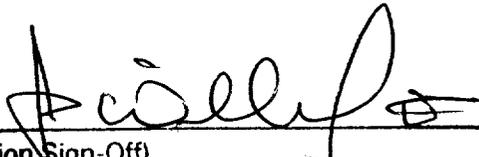
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)



 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K990598