K990849

DEC 20 1999

510(k) Summary

Proprietary Name: Duration® IV Sterilization / Stabilization Process (System 12® Acetabular Inserts, Omnifit® and Trident™ Acetabular Inserts)

Common Name: Modular Acetabular Inserts

Classification Name and Reference: 21 CFR 888.3353
Hip Joint Metal/Ceramic/Polymer,Semi-Constrained
Cemented or uncemented prosthesis

Proposed Regulatory Class: Class II

Device Product Code: JDI OR(87)

For information contact: Frank Maas
Manager, Regulatory Affairs
Howmedica Osteonics Corp.
359 Veterans Boulevard
Rutherford, NJ 07070
Telephone: (201) 507-7875
Fax: (201) 507-6870
Date Summary Prepared: 3/12/99

The purpose of this submission is to describe additional styles of System 12® Acetabular, Omnifit® and Trident™ Acetabular Inserts which are sterilized/ stabilized using a process called Duration® IV Stabilization. The purpose of the Duration® IV process is to minimize (through crosslinking) the free radicals found in the UHMWPE rod stock by exposure to gamma radiation followed by a stabilization process in a heated oven. The stabilized rod stock is then machined to its final configuration. The components are packaged in air, and terminally sterilized by either Gas Plasma or Ethylene Oxide sterilization. The components produced by this method conform to the requirements for Ultra High Molecular Weight Polyethylene specified in ASTM Specification F-648, and the FDA guidance document on UHMWPE used in Bearing Surfaces for Orthopedic Devices.

The intended use of the additional styles of components referenced above is identical to that of the previously released components. The System 12®, Omnifit®, and Trident™ acetabular inserts are intended to be used with their respective acetabular shells in primary or revision total hip arthroplasty.

Testing was performed in accordance with the draft FDA guidance on UHMWPE.

The following marketing claims will be made for the products:

1. Duration® IV products meet all ASTM F-648 specified standards.

2. Duration® IV products have no detectable oxidation as measured by FTIR up to 23 days of accelerated aging at 80°C in air.

3. Duration® IV products have a higher cross-linking density than air irradiated UHMWPE measured in accordance with modified ASTM D2765-90 standard.

4. Duration® IV has a lower tensile modulus than air irradiated UHMWPE. This lower stiffness has demonstrated an increase in contact area and a decrease in contact stress.

5. No free radicals are detected in the Duration® IV material when analyzed by the ESR technique of the final product.

6. Duration® IV has a 91% lower wear rate, as measured by hip wear simulation testing under non-abrasive conditions, than UHMWPE that is gamma sterilized in an inert atmosphere (an average total wear of 22.8 ± 13.7mm^3 instead of 258.8 ± 39.7 mm^3). Testing was performed in a multiaxial hip joint simulator for 5.0 million cycles using a 32 mm CoCr head articulating counterface against a 4.8 mm thickness polyethylene insert with bovine calf serum used as a lubricant. The results of *in vitro* tests have not been shown to correlate with clinical wear mechanisms.

7. Duration® IV has a 98% lower wear rate, as measured by hip wear simulation testing under abrasive conditions, than UHMWPE that is gamma sterilized in an inert atmosphere (an average total wear of 2.2 ± 2.2 mm^3 instead of 89.9 ± 4.0 mm^3). Testing was performed in a multiaxial hip joint simulator for 3.5 million cycles using a 32 mm CoCr head articulating counterface against a 4.8 mm thickness polyethylene insert with bovine calf serum used as a lubricant and PMMA bone cement particles as the abrasive media.. The results of *in vitro* tests have not been shown to correlate with clinical wear mechanisms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 1999

Mr. Frank Maas
Manager, Regulatory Affairs
Howmedica Osteonics Corporation
359 Veterans Blvd.
Rutherford, New Jersey 07070

Re: K990849
Trade Name: Duration IV Sterilization Process (Acetabular Inserts)
Regulatory Class: II
Product Code: LPH and JDI
Dated: September 13, 1999
Received: September 30, 1999

Dear Mr. Maas:

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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard
Acting Division Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K990849

Device Name: System 12®, Omnifit®, & Trident™ Acetabular Inserts

Indications for Use:

The intended use of the additional styles of the System 12®, Omnifit®, & Trident™ acetabular inserts is identical to that of previously released inserts: they are intended to be used with their respective acetabular shells in primary or revision total hip arthroplasty.

NRO for

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990849

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 21 CFR 801.109 OR Over-The-Counter Use No
(Per 21 CFR 801.109)

(Optional Format 1-2-96)