

DEC 11 1998

K980626
510(k) Summary

Device: Duration® II System 12® Acetabular Inserts - Gas Plasma Sterilization

The purpose of this submission is to describe an additional style of System 12® acetabular inserts which are stabilized/sterilized using a process called Duration® II Stabilization. The purpose of the Duration® II process is to crosslink all of the free radicals found in the UHMWPE rod stock by exposure to gamma radiation followed by a stabilization process in a heated oven. During this radiation/stabilization period, the UHMWPE is exposed to a very low oxygen concentration. The stabilized rod stock is then machined to its final configuration. The acetabular insert is packaged in air, and terminally sterilized by the gas plasma sterilization process. The System 12® Acetabular Inserts 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 this additional style of System 12® acetabular inserts is identical to that of previously released System 12® inserts: they are intended to be used with Osteolock/Vitalock acetabular shells in primary or revision total hip arthroplasty.

These System 12® inserts are identical in design to previously cleared System 12® inserts: they are available in a range of outer diameter sizes to mate with the respective acetabular shell, and 22.0, 22.2, 26, 28, and 32mm inner diameters to mate with Howmedica femoral heads. These inserts are available in a neutral, 10°, and 15° hooded design. The locking mechanism of this style of acetabular insert is identical to previously released System 12® acetabular inserts.

These inserts are substantially equivalent to the other System 12® acetabular liners which are already in distribution by Howmedica.

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

The following marketing claims will be made for the product:

1. Duration® II products meet all ASTM F 648 specified standards
2. Duration® II products have no detectable oxidation as measured by FTIR up to 30 days of accelerated aging at 80° C in air.
3. Duration® II products have a higher gel content (cross-linking) than air irradiated UHMWPE measured in accordance with modified ASTM D2765-90 standard.
4. Duration® II 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® II material when analyzed by the ESR technique of the final product.
6. Duration® II has a lower wear rate, as measured by hip wear simulator than air irradiated UHMWPE (an average total wear of $168.60 \pm 50.71 \text{ mm}^3$ instead of $310 \pm 40.8 \text{ mm}^3$). Testing was performed in a multiaxial hip joint simulator for five million cycles using a 32 mm CoCr head articulating counterface and bovine calf serum as a lubricant. The results of *in vitro* tests have not been shown to correlate with clinical wear mechanisms.

For information contact: Frank Maas
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Howmedica Osteonics.
359 Veterans Boulevard
Rutherford, NJ 07070
(201) 507-7875



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 1998

Mr. Frank Maas
Manager, Regulatory Affairs
Howmedica Inc.
Pfizer Medical Technology Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K980626
Trade Name: Duration® II Acetabular
Components - Gas Plasma Sterilization
K980632
Trade Name: Duration II Tibial
Inserts - Gas Plasma Sterilization
Regulatory Class: II
Product Code: JDI, LPH, and JWH
Dated: September 18, 1998
Received: September 18, 1998

Dear Mr. Maas:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) 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 devices, 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.

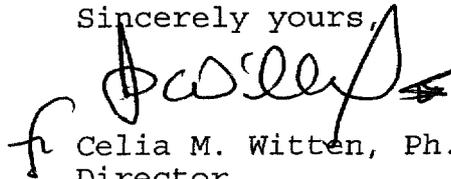
If your devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

action. In addition, FDA may publish further announcements concerning your devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,

A handwritten signature in black ink, appearing to read "C. Witten", with a large initial "f" to the left.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): K980626

Device Name: Duration® II System 12® Acetabular Inserts - Gas Plasma Sterilization

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use NA
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)

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

K980626