

OCT 16 1997

510(k) Summary

K972792

Proprietary Name: Duration® Stabilized UHMWPE Acetabular Components

Common Name: UHMWPE Acetabular Components

Classification Name and Reference: 21 CFR 888.3358

Proposed Regulatory Class: Class II

Device Product Code: JDI

For information contact: Frank Maas
Manager, Regulatory Affairs
Howmedica Inc.
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Date Summary Prepared: 7-25-97

This submission describes additional UHMWPE acetabular components that can be sterilized by the Duration® Stabilized process previously cleared in submission K934060, as an alternate to standard air irradiated gamma sterilization. The additional components are the Exeter All Plastic Acetabular Component (K936132) and the Howmedica® Bipolar Prosthesis, Centrax® (K855231). Corresponding wear claims, previously cleared in submission K 963612 and listed below, are also applicable to these additional components.

Howmedica's Duration® Stabilized UHMWPE, System 12®, size P4, neutral acetabular inserts, with an inner diameter of 32mm, a bearing thickness of 6.1 mm and aged for 6 months in an oxygen environment, showed a 36% reduction in volumetric wear **versus** the same cup conventionally gamma sterilized and aged for 6 months in an oxygen environment. Testing was performed in a multiaxial hip joint simulator for over 10 million cycles, using a 32mm 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.

Howmedica's Duration® Stabilized UHMWPE, a hemispherical cup of generic design for hip simulator testing, with an inner diameter of 32 mm, and a bearing thickness of 8.4 mm, showed a 40% reduction in volumetric wear versus the same cup conventionally gamma sterilized. Testing was performed in a multiaxial hip joint wear simulator for over 5 million cycles, using a 32 mm diameter CoCr Head articulating counterface and low calcium" containing bovine calf serum as a lubricant. The results of *in vitro* tests have not been shown to correlate with clinical wear mechanisms.

Howmedica's Duration® Stabilized UHMWPE, System 12® Neutral Acetabular Insert, size P4, with an inner diameter of 32mm, and a bearing thickness of 6.1 mm, showed a 40% reduction in volumetric wear versus the same cup conventionally gamma sterilized. Testing was performed in a hip joint wear simulator for over 5 million cycles, using a 32 mm CoCr Head articulating counterface and high calcium" containing bovine calf serum as a lubricant. The results of these *in vitro* tests have not been shown to correlate with clinical wear mechanisms or *in vitro* third body wear mechanisms involving fragments of bone, bone cement, UHMWPE , metal, ceramic, etc.

In an independent laboratory test on Howmedica's Duration® Stabilized UHMWPE, a hemispherical cup of generic design for hip simulator testing, with an inner diameter of 32 mm, a bearing thickness of 8.4 mm, and having undergone 11 days of heating in air to simulate 5 years "aging", showed a 27% reduction in volumetric wear versus the same cup conventionally gamma sterilized, having undergone 11 days of heating in air to simulate 5 years "aging". Testing was performed in a multiaxial hip joint wear simulator over 10 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frank Maas
Manager, Regulatory Affairs
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Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070

OCT 16 1997

Re: K972792
Trade Name: Duration Stabilized UHMWPE Exeter All
Plastic Acetabular Component and Centrex®
Bipolar Component
Regulatory Class: II
Product Codes: JDI and KWY
Dated: July 25, 1997
Received: July 28, 1997

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.

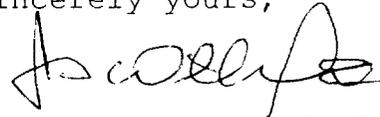
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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


f 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

K972792
Indications for Use

510(k) Number (if known):

Device Name: Duration® Stabilized UHMWPE Acetabular Components

Indications for Use:

The Exeter All Plastic Acetabular Component (previously cleared in K936132) is intended to be used for primary and secondary reconstruction of the bearing surface of the acetabulum as a result of painful and/or severely disabled hip joints due to osteoarthritis, rheumatoid arthritis, post-traumatic arthritis or revision of a failed acetabular component.

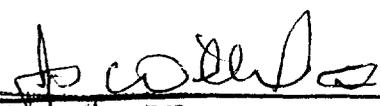
The Howmedica® Bipolar Prosthesis, Centrax® (previously cleared in K855231) is intended to be used in conjunction with a femoral stem component for the reconstruction of a femoral head damaged by fresh fracture, non-union, aseptic necrosis of the head and neck, or by osteoarthritis or post-traumatic arthritis.

SEE NEXT PAGE FOR DURATION® WEAR CLAIMS

(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)


(Division Sign-Off) (Optional Format 1-2-96)
D General Restorative Devices
510(k) number K972792