

DURATION™ WEAR CLAIMS - HIP COMPONENTS
K963612

June 11, 1997

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.

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.

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Food and Drug Administration
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Rockville MD 20850

JUN 11 1997

Mr. John F. Dichiaro
Manager, Regulatory Affairs
Howmedica Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

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Re: K963612
Duration™ Stabilized UHMWPE - Hip Components
K965173
Duration™ Stabilized UHMWPE - Knee Components
Regulatory Class: II
Product Codes: JDI, LPH, JWH, and HRY
Dated: March 21, 1997
Received: March 25, 1997

Dear Mr. Dichiaro:

We have reviewed your Section 510(k) notification 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 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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 devices in the Federal Register. Please note: this response to your pre-market notification submission does not affect any

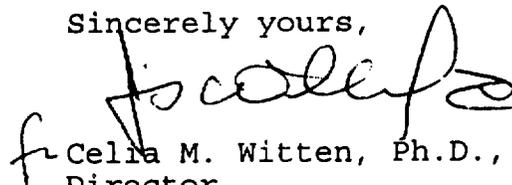
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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,



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): K963612

Device Name: Duration™ Stabilized UHMWPE (Wear Data - Hip Components)

Indications for Use:

The P.C.A.® System Inserts (previously cleared in K921384) are intended to be used with P.C.A.® Acetabular Shells, and Howmedica femoral stems and heads in cementless primary or cemented primary/revision total hip arthroplasty.

The Premise® Hip Acetabular Components (previously cleared in K912426) are intended to be used with Howmedica femoral stems and heads in cemented primary or revision total hip arthroplasty.

The Osteolock™ Inserts (previously cleared in K903362), and the System 12® inserts (previously cleared in K951114 and K951115), when used with the Osteolock™ and Vitalock® Shells, are intended to be used with Howmedica femoral stems and heads in cemented primary of revision total hip arthroplasty.

SEE ADDITIONAL PAGE LABELED 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)

(Optional Format 1-2-96)

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

K963612