K965173

June 11, 1997

510(K) SUMMARY

Trade Name: Duration™ Stabilized UHMWPE Knee Components

Common Name: UHMWPE Knee Components

This submission includes wear testing data on UHMWPE Knee Components sterilized by the method previously cleared in 510(k) submission K936292. This data is provided to substantiate claims of improved wear due to the processing of the devices. The submission includes Duracon®, P.C.A.® and Kinemax® Plus Tibial Inserts, All Plastic Tibial Components and Patellar Components which are intended to be used with Duracon®, P.C.A.® or Kinemax® Plus femoral components, tibial baseplates and patellar components in primary or revision cemented total knee arthroplasty.

The following are the wear claims that will be made for these devices:

A block of Howmedica's Duration™ Stabilized UHMWPE showed a 30% reduction in volumetric wear versus the same block of Howmedica's conventionally gamma sterilized UHMWPE. Testing was performed in a reciprocating ring-on-block wear test for over 5 million cycles, using a circular disk, 2.83" in diameter, 1" wide, CoCr 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, a 9mm thick circular disk of Howmedica's Duration™ Stabilized UHMWPE showed a 68% reduction in volumetric wear versus the same circular disk of Howmedica's conventionally gamma sterilized UHMWPE. Testing was performed in a reciprocating pin-on-disk wear evaluation over 4 million cycles, using a CoCr cylindrical pin with a 1" spherical end as the 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, a 9 mm thick circular disk of Howmedica's Duration™ Stabilized UHMWPE, having undergone 23 days of heating in air to simulate 7-9 years of "aging", showed a 91% reduction in volumetric wear versus the same circular disk of Howmedica's conventionally gamma sterilized UHMWPE, having undergone 23 days of heating in air to simulate 7-9 years of "aging". Testing was performed in a

reciprocating pin-on-disk wear evaluations over 2.5 million cycles, using a CoCr cylindrical pin with a 1" spherical end as the 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: John Dichiara
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Howmedica Inc.
359 Veterans Boulevard
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DURATION™ WEAR CLAIMS - KNEE COMPONENTS
K965173

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1997

Mr. John Dichiara
Regulatory Affairs Manager
Howmedica Inc.
Division of Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070

Re: K965173
Trade Name: Duration Stabilized UHMWPE - Knee Components
Regulatory Class: II
Product Codes: JWH and HRY
Dated: March 21, 1997
Received: March 25, 1997

Dear Mr. Dichiara:

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.

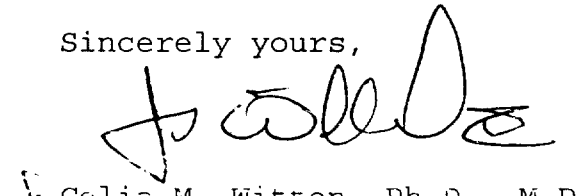
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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



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

Indications for Use

510(k) Number (if known): K965173

Device Name: Duration™ Stabilized UHMWPE Knee Components

Indications for Use:

The Duracon®, P.C.A.® and Kinemax® Plus Tibial Inserts, All Plastic Tibial Components and Patellar Components (previously cleared in K915512, K923573, K910235, K922048, K932070, K913188, K872735, K871772 and K921640) are intended to be used with Duracon®, P.C.A.® or Kinemax® femoral components, tibial baseplates and patellar components in primary or revision cemented total knee 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 (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 K965173