

K97 2863

510(k) Summary

Proprietary Name: Duration® Stabilized UHMWPE Knee Components

Common Name: UHMWPE Knee Components

OCT 29 1997

Classification Name and Reference: 21 CFR 888.3560

Proposed Regulatory Class: Class II

Device Product Code: JWH

For information contact: Frank Maas
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
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Fax: (201) 507-6870
Date Summary Prepared: 8-1-97

This submission describes additional UHMWPE Knee components that can be sterilized by the Duration® Stabilized process previously cleared in submission K936292, as an alternate to standard air irradiated gamma sterilization. Corresponding wear claims, previously cleared in submission K 965173 and listed below, are also applicable to these additional components.

This submission includes the Kinemax® Superstabilizer (K904208), the Kinematic® II Modular Condylar and Stabilizer Inserts (K871349), the PCA Modular Inserts (K894403), the Kinematic® Rotating Hinge Knee (K792089), the Duracon® Unicompartamental Knee (K926231), and the Modular Replacement Metal Encapsulated Components (K952970). These components are intended to be used with the PCA®, Duracon®, or Kinemax® family of femoral components, tibial baseplates, and patellar components in primary or revision cemented total knee arthroplasty.

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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT 29 1997

Re: K972863
Trade Name: Duration® Stabilized UHMWPE
Knee Components
Regulatory Class: II
Product Code: JWH
Dated: August 1, 1997
Received: August 4, 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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.
2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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.

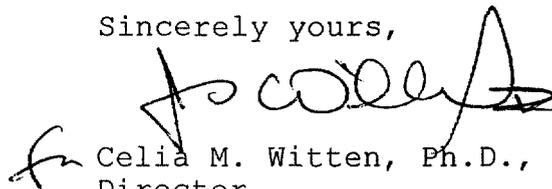
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

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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

K972863

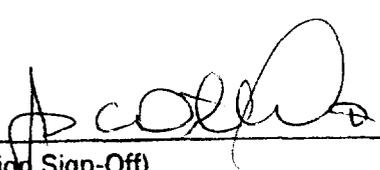
DURATION® WEAR CLAIMS - KNEE COMPONENTS

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.

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Prescription Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number _____

K972863

Indications for Use

K972863

510(k) Number (if known):

Device Name: Duration® Stabilized UHMWPE Knee Components

Indications for Use:

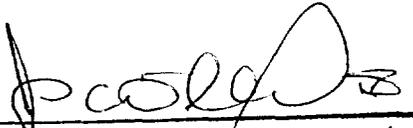
The Kinemax® Superstabilizer (K904208), Kinematic® II Modular Condylar and Stabilizer Inserts (K871349), PCA® Modular Inserts (K894403), Kinematic® Rotating Hinge Knee (K792089), Duracon® Unicompartamental Knee (K 926231), and the Modular Replacement Metal Encapsulated Components (K952970) are intended to be used with the PCA®, Duracon®, or Kinemax® family of femoral components, tibial baseplates, and patellar components in primary or revision cemented total knee arthroplasty.

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 OR Over-The-Counter Use
(Per 21 CFR 801.109)


(Division Sign-Off) (Optional Format 1-2-96)
Division of General Restorative Devices

510(k) Number K972863