K993692

DEC - 2 1999

510(k) Summary

Duracon Inset Patellar Component: Additional Size

Submission Information

Name and Address of the Sponsor:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Terry Sheridan Powell
Date of Summary Preparation:	October 29, 1999

Device Identification

Proprietary Name:	Duracon Inset Patellar Component
Common Name:	Artificial Knee Component
Classification Name and Reference:	888.3560: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

Predicate Device Identification

The Duracon Inset Patellar Component, in sizes 27, 29, 31, and 33mm, were determined Substantially Equivalent via 510(k) #K961482. They were then cleared in a Duration-stabilized version via K965173. This Special 510(k) covers an additional size component: 25mm.

Intended Use

The intended use of the subject component is unchanged from that of the commercially-available Duracon Inset Patellar Components. The indications are specified in the Indications for Use attachment, and are the same as those cleared via K961482.

Device Description

The subject 25mm Duracon Inset Patellar Component is identical to the commercially-available Duracon Inset Patellar Components (available in sizes 27, 29, 31, and 33mm), except for its smaller diameter.

Statement of Technological Comparison

The materials for the subject and predicate devices are identical. The indications for use of the subject and predicate devices are identical. The design of the subject and predicate devices is the same, except that the subject device is a new, smaller size: 25mm diameter. The performance testing is sufficient to demonstrate that the subject and predicate devices are Substantially Equivalent with regard to design.

Performance Data

Comparative testing (simulated chair rising and stair climbing) confirmed that the wear resistance of the modified component is not significantly different from that of existing product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 1999

Ms. Terry Sheridan Powell
Regulatory Affairs Department
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K993692
Trade Name: Duracon Inset Patella, 25mm
Regulatory Class: II
Product Code: JWH
Dated: October 29, 1999
Received: November 2, 1999

Dear Ms. Powell:

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 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,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 993692

Device Name: Duracon Inset Patellar Component, Additional Size (25mm)

Indications For Use:

The subject devices are single use components, intended for cemented use only. They are intended for use in conjunction with associated Duracon femoral components as part of cemented total knee replacement surgery. Indications for use, in keeping with those of other commercially-available, Class II total knee devices, are as follows:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis.
- Rheumatoid arthritis.
- Correction of functional deformity.
- Revision procedures where other treatments have failed.
- Post-traumatic loss of knee joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy.
- Irreparable fracture of the knee.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

ARD for

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993692

Prescription Use Y
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)