OCT 18 2002

510(k) Summary

Submission Information

Name and Address of Sponsor:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401
For Information contact:	Margaret F. Crowe Regulatory Affairs Consultant Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401

Device Identification

Proprietary Name:	Duracon® CS Tibial Insert
Common Name:	Polyethylene Tibial Insert
Classification Name and Reference:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis 21 CFR §888.3560
Proposed Regulatory Class:	Class II
Device Product Code:	OR(87) JWH Prosthesis, Knee Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/ Polymer

The Duracon® CS (Condylar Stabilizing) Tibial Inserts are intended to be used with Duracon® Universal and Cruciform tibial baseplates, Duracon® Cruciate Retaining femoral components and Duracon® patellar components as part of a total knee system in primary cemented total knee arthroplasty. These inserts are intended to be used in cases where there is destruction of the joint surfaces with or without bone deformity, where the cruciate ligaments are inadequate, not present, or cannot be preserved during the operative procedure, especially when anterior-posterior stability is impaired due to absence of the patella. The collateral ligaments should be intact if this insert is utilized.

This tibial insert may also be used in situations where the posterior cruciate ligament is present - its geometry will accommodate that ligament. More specific indications and contraindications are listed below:

Indications

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee

Contraindications

Absolute contraindications include:

- Overt infection,
- Distant foci of infections (which may cause hematogenous spread to the implant site),
- Rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram,
- Skeletally immature patients
- Cases where there is poor bone stock which would make the procedure unjustifiable,

Conditions presenting an increased risk of failure include:

- Uncooperative patient or patient with neurological disorders who is incapable of following instructions,
- Osteoporosis,
- Metabolic disorders which may impair bone formation,
- Osteomalacia, and
- Previous arthrodesis

The subject Duracon® CS Tibial Insert is an ultra-high molecular weight polyethylene tibial insert designed to be used with the femoral, tibial, and patellar components of the

Duracon® Total Knee System. This insert is available in small, medium, large, and extra-large sizes in the following thicknesses: 9mm, 11mm, 13mm, 16m, 19mm, 22mm, and 25mm. The subject insert has a dished articulating surface geometry to provide anatomic rollback, flexion-extension and internal-external rotation. The subject tibial insert features a raised anterior eminence designed to provide greater anterior constraint in situations where the posterior cruciate ligament is not present or not functional. This anterior eminence is designed to provide substitution for the posterior cruciate ligament if it is not present or cannot be preserved. The subject insert provides approximately 37 percent more constraint than the predicate Duracon® AP Lipped Tibial Insert, without any increase in rotational constraint.

The subject insert does not feature a support post. This allows the Duracon® Condylar Stabilizing (CS) Lipped Tibial Insert to be used with the Duracon® Condylar Femoral Components. These condylar femoral components do not require the removal of additional bone from the distal surface of the femur. Because this insert does not feature a support post, it may also be used in situations where the posterior cruciate ligament is present. The geometry of the insert will accommodate the PCL if it is present.

The subject Duracon® CS Tibial Insert features the same locking mechanism as the previously released Duracon® Condylar and AP Lipped Tibial Insert.

Testing was presented to characterize the function of the subject tibial insert, and to demonstrate substantial equivalence to other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2002

Ms. Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401

Re: K021451
Trade/Device Name: Duracon® CS Lipped Tibial Insert
Regulation Number: 21 CFR §888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: August 2, 2002
Received: August 5, 2002

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

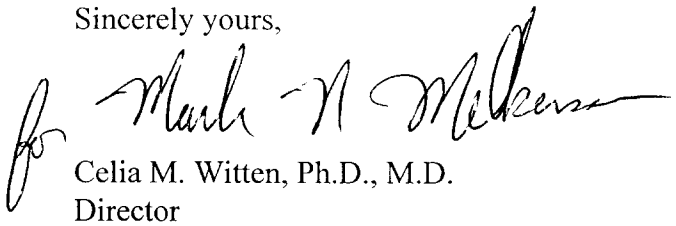
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021451

Device Name: Duracon® CS Lipped Tibial Insert

The Duracon® CS (Condylar Stabilizing) Tibial Inserts are intended to be used with Duracon® Universal and Cruciform tibial baseplates, Duracon® Cruciate Retaining femoral components and Duracon® patellar components as part of a total knee system in primary cemented total knee arthroplasty. These inserts are intended to be used in cases where there is destruction of the joint surfaces with or without bone deformity, where the cruciate ligaments are inadequate, not present, or cannot be preserved during the operative procedure, especially when anterior-posterior stability is impaired due to absence of the patella. The collateral ligaments should be intact if this insert is utilized. Because this insert does not incorporate a support post, it can accommodate the posterior cruciate ligament if it is present. More specific indications/contraindications are listed below:

Indications

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- 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)

Prescription Use _____ OR Over-the-Counter Use _____ (per 21 CFR 801.109)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021451