

APR 6 2000

K983657

Howmedica Osteonics® Series 7000 AD Tibial Tray

510(k) Summary

**510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Howmedica Osteonics® Series 7000 AD Tibial Tray**

Submission Information

Name and Address of the Sponsor
of the 510(k) Submission:

Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Contact Person:

Mary-Catherine Dillon
Regulatory Affairs Specialist

Date of Summary Preparation:

March 31, 2000

Device Identification

Proprietary Name:

Howmedica Osteonics® Series 7000
AD Tibial Tray

Common Name:

Total Knee Tibial Component

Classification Name and Reference:

Knee Joint Femorotibial
Metal/Polymer Semi-Constrained
Cemented Prosthesis
21 CFR §888.3530

Predicate Device Identification

The Howmedica Osteonics® Series 7000 AD Tibial Tray is substantially equivalent to the following competitive and/or Howmedica Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Howmedica Osteonics® Series 7000 Total Knee System Tibial Components
- Howmedica Osteonics® Omniflex™ AD Hip Stem
- The Maxim® Complete Knee System - Biomet, Inc.

Device Description

Howmedica Osteonics® Series 7000 AD Tibial Trays are intended for cemented fixation on the prepared proximal tibia and are designed to achieve total reconstructive replacement of the knee joint when used in conjunction with the Howmedica Osteonics® Total Knee Femoral, Patellar and Tibial Insert Components. The metallic tibial tray is manufactured from ASTM F75-92 CoCr alloy. The "pocketless" design of the fixation surface employs a roughened, arc-deposited ASTM F67-95 CP Titanium coating. The keeled stems of the Howmedica Osteonics® Series 7000 AD Tibial Tray employ a satin finish and arc not coated with arc-deposited CP Titanium. Screw hole plugs, fabricated from low density polyethylene (LDPE), are located in the tibial tray screw holes.

Intended Use:

The Howmedica Osteonics® Series 7000 AD Tibial Tray is intended to be marketed for cemented fixation only and may be used with any of the following UHMWPE tibial bearing inserts, which range in thickness from 8mm to 24mm:

- Howmedica Osteonics® Tibial Bearing Insert - Series I
- Howmedica Osteonics® Tibial Bearing Insert - Series II
- Howmedica Osteonics® Series 7000 Total Knee Tibial Bearing Insert - Series P/S- I
- Howmedica Osteonics® Scorpio Total Knee Posteriorly Stabilized Tibial Bearing Insert
- Howmedica Osteonics® Scorpio Total Knee Cruciate Retaining Tibial Bearing Insert

If supplemental bone screw fixation of the tray is deemed necessary, Howmedica Osteonics® 6.5mm Cancellous Bone Screws may be placed through the tibial tray screw holes.

Indications:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.

Additional Indications for Posterior Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Contraindications:

The contraindications for the Howmedica Osteonics® Series 7000 AD Tibial Tray include:

- Any active or suspected latent infection in or about the knee joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.

- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.

Statement of Technological Comparison:

The subject device is identical to the tibial tray of the predicate Howmedica Osteonics® Series 7000 Total Knee Tibial Components in all material and design aspects, indications, shape and intended use, with the exception of the arc-deposited CP Titanium coating and the absence of a “pocket” on the inferior side of the tray. The arc-deposited CP Titanium coating on the inferior side of the tibial tray is identical to the AD coating on the predicate Howmedica Osteonics® Omniflex™ AD Hip Stem.

Howmedica Osteonics’ CP Titanium coating is arc-deposited onto the surface of CoCr substrate. The combination of a CoCr substrate with CP Titanium coating on the Howmedica Osteonics® Series 7000 AD Tibial Tray is similar to that of the predicate Maxim® Complete Knee System manufactured by Biomet, Inc., which offers a CoCr substrate coated with Titanium alloy.

Summary

Based on the information presented above in combination with a Coating Characterization Summary, and the fact that the Howmedica Osteonics® Series 7000 AD Tibial Trays employ standard sterilization and packaging methods, the substantial equivalence of the Howmedica Osteonics® Series 7000 AD Tibial Trays to other legally marketed, class II total knee components is demonstrated.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mary-Catherine Dillon
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401-1677

Re: K983657

Trade Name: Howmedica Osteonics® Series 7000 AD Tibial Tray
Regulatory Class: II
Product Code: HRY and JWH
Dated: January 24, 2000
Received: January 28, 2000

Dear Ms. Dillon:

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 control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

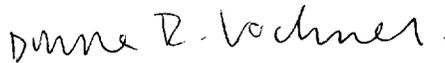
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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 at (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

510(k) Number (if known): K 983657

Device Name: Howmedica Osteonics® Series 7000 AD Tibial Tray

Indications For Use:

The subject devices are single use components, intended for cemented use only. The indications for the use of these tibial trays, in keeping with those of other legally marketed Howmedica Osteonics tibial trays, are as follows:

Indications:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.

Additional Indications for Posterior Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vachner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983657

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)