K030809

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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: Scorpio® Low Profile Tibial Tray

Common Name: Modular Tibial Tray

Classification Name and Reference: Knee Joint; Patellofemorotibial; Polymer/metal/polymer; Semi-constrained; Cemented prosthesis - Class II - 21 CFR 888.3560

Proposed Regulatory Class: Class II

Device Product Code: OR(87) JWH

Intended Use

The Scorpio® Low Profile Tibial Tray is intended to be used with commercially available Scorpio® Cruciate Retaining femoral components, Scorpio® CR and ScorpioFlex CR tibial bearing inserts, and Scorpio® patellar components in primary cemented total knee arthroplasty. The indications/contraindications for the Scorpio® Low Profile Tibial Tray are outlined below:

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.

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Contraindications

- 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.
- The use of bone augmentations is contraindicated with the Scorpio® Low Profile Tibial Tray

Device Description

The Scorpio® Low Profile Tibial Tray is a sterile, single-use device that is intended to be used with Scorpio® CR femoral components and associated patellar components, and Scorpio® CR and ScorpioFlex CR tibial bearing inserts in primary cemented total knee arthroplasty. The subject Scorpio® Low Profile Tibial Tray is identical in design to the previously cleared Series 7000 Standard Tibial Tray (found substantially equivalent in premarket notification K 910990) with the following exception: the length of the keel has been decreased to 0.50 inches to allow the implant to be inserted through a smaller incision.

The subject Scorpio® Low Profile Tibial Tray is fabricated from cast cobalt-chromium alloy that conforms to ASTM specification F-75. This tibial tray is offered in eight proportional sizes (sizes 3, 4, 5, 6, 7, 9, 11 and 13) and features the same barb and wire

locking mechanism as the previously released Series 7000 Standard tibial tray. The undersurface of the tibial tray has a cast-in waffle surface feature to enhance cement fixation. The waffle pattern interior surface is not an applied coating, but is cast into the cobalt chromium alloy substrate, and consists of a series of pyramids separated by a distance of 0.53mm, with a pyramid angle of 18°. The keel of the tibial tray utilizes the delta fit keel (swept back normalizations) to provide rotational stability and enhance cement fixation.

Equivalent products include: Series 7000 Tibial Tray (K910990); Duracon® Cruciform Tibial Tray (K926228); and Interax Modular Tibial Tray (K973121).

Finite element analysis was presented to support substantial equivalence to a predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2003

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

Re: K032829
Trade/Device Name: Scorpio® Low Profile Tibial Tray
Regulation Numbers: 21 CFR 888.3560
Regulation Names: Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JWH
Dated: September 10, 2003
Received: September 11, 2003

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.

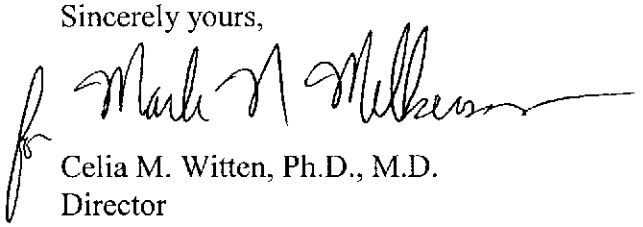
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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): K032829

Device Name: Scorpio® Low Profile Tibial Tray

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(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)
(Optional Format 1-2-96)

for

...ative
...ological Devices

...) Number K032829