

K 041591

SEP 23 2004

**Special 510(k) Summary of Safety and Effectiveness:
Design Modification to the Scorpio® -Flex Posterior Stabilized Tibial Insert Components**

Proprietary Name: Scorpio®-Flex Posterior Stabilized Tibial Insert Components

Proposed Regulatory Class: Class II

Classification: Knee Joint; Patellofemorotibial; Polymer/metal/polymer; Semi-constrained; Cemented prosthesis: 21 CFR 888.3560

Device Product Code: 87 JWH

For Information contact: Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
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Date Summary Prepared: June 9, 2004

Predicate Device Identification:

The Scorpio® Total Knee System consists of various sizes of femoral, tibial and patellar components.

Description of Device Modification:

This submission is intended to address a design modification to the Scorpio®-Flex Posterior Stabilized Tibial Insert components. The tibial insert components have been redesigned to provide for improved hyperextension. There has been no change to the intended use of the device.

Indications for Use:

The Scorpio®-Flex Posterior Stabilized Tibial Insert components are for use in total knee arthroplasty for 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 with the ligamentous structures can be returned to adequate function and stability; and/or revision of previous unsuccessful knee replacement or other procedure, ligamentous instability requiring implant bearing surface geometries with increased constraint; and absent or non-functioning posterior cruciate ligament.

Statement of Technological Comparison:

The subject components share the same intended use and basic design concept as that of the predicate devices. A risk analysis, testing and analysis have been performed to demonstrate equivalence of the subject device to the predicate device. The testing includes range of constraint testing, analysis of tibial insert post stress and contact stress/area analysis. The results demonstrate equivalence.



SEP 23 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K041591

Trade/Device Name: Scorpio[®]-Flex Posterior Stabilized Tibial Inserts

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Regulatory Class: II

Product Code: JWH

Dated: August 25, 2004

Received: August 26, 2004

Dear Ms. Ariemma:

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.

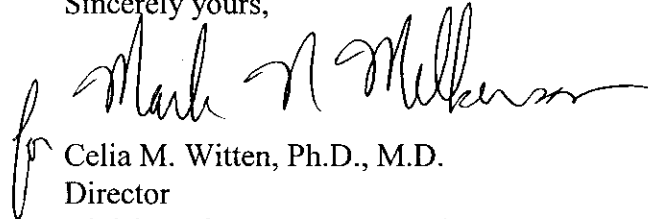
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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): K041591

Device Name: Scorpio®-Flex Posterior Stabilized Tibial Insert

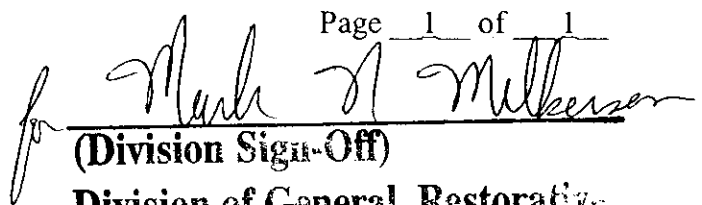
Indications

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

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K041591