

JAN 15 2004

Summary of Safety and Effectiveness

Contact Person: Denise Duchene
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Howmedica Osteonics Corp.
59 Route 17 South
Allendale, NJ 07401
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Date: September 17, 2003

Device: Scorpio® Knee System – Tibial Inserts

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

Predicate Devices: Scorpio® Knee System - Tibial Inserts

Indications for Use: The Scorpio® Knee System 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 which the ligamentous structures can be returned to adequate function and stability; and/or revision of previous unsuccessful knee replacement or other procedure.

Proposed Modification: Redesign of the tibial insert component dimensions to provide for improved hyperextension. In addition, to provide a claim for the CR insert that indicates it provides sufficient constraint for use when the posterior cruciate ligament (PCL) is absent or non-functioning.

Device Description: The device includes the tibial insert components of a total knee system. These components are used for the replacement of the bearing surface of the proximal tibia to relieve pain, instability and the restriction of motion due to degenerative bone disease, including osteoarthritis, rheumatoid arthritis, failure of other devices or trauma.

Summary of Data: A risk analysis and Research and Development testing have been performed to demonstrate equivalence of the proposed products to the predicate devices. The testing includes range of constraint testing, analysis of tibial insert post stress and contact stress/area analysis. The results demonstrate equivalence.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 15 2004

Ms. Lorraine T. Montemurro
Regulatory Affairs Manager
Stryker Howmedica Osteonics
59 Route 17 South
Allendale, New Jersey 07401

Re: K033342

Trade/Device Name: Scorpio[®] Knee System – Tibial Inserts

Regulation Number: 21 CFR 888.3560

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

Regulatory Class: II

Product Codes: JWH

Dated: October 15, 2003

Received: October 17, 2003

Dear Ms. Montemurro:

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.

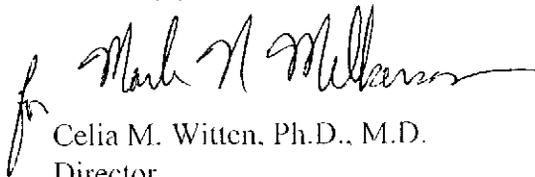
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 fluid and cursive, with a long horizontal stroke at the end.

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

