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510(K) SUMMARY

Scorpio® Inset Patellar Component

The Scorpio® Inset Patellar Component is intended to articulate with any commercially available Scorpio® Total Knee Femoral Component (Scorpio® PS Femoral Component – premarket notification K962152; Scorpio® CR Femoral Component – premarket notification K974556, and Scorpio® TS Femoral Component – premarket notification K994128), any commercially available Osteonics® Series 7000 Total Knee Femoral component (premarket notifications K912147, K914565, K925372, K941128, K944285) and any commercially available Osteonics® Omnifit® Total Knee Femoral Component (premarket notifications K862837, K863668, K884410, and K910989). The subject patellar components are single use devices, intended for cemented applications on the surgically prepared posterior patella as part of primary or revision cemented total knee arthroplasty. This component replaces the patellar articulating surface of the knee joint to simulate the normal function of the knee.

The indications and contraindications for the use of the Scorpio® Inset Patellar Component in conjunction with a total knee replacement, in keeping with those of other legally marketed Class II patellar components, 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.

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Contraindications:

The contraindications for the subject devices 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.

Device Description

The Scorpio® Inset Patellar Component is fabricated from ultra-high molecular weight polyethylene (UHMWPE). The component is available in one thickness (10mm) and four diameters (26mm, 28mm, 30mm, and 32mm). The overall geometry essentially consists of a circular patellar button configuration with a central peg on the anterior surface of the component. The anterior surface also features a pocket and undercuts for cement interdigitation. The subject Scorpio® Inset Patellar Component is mounted to the surface of the surgically prepared patella within a recessed hole when cementing the component into place.

The articular (posterior) surface of this component is identical to the articular surface of the Osteonics® Recessed Patellar Component, found substantially equivalent in premarket

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notification K863668, and cleared for use with Scorpio® femoral components in K962152. The anterior (bone fixation) surface is similar to that of the Duracon® Recessed Patellar Component (#K951655). The Duracon® Recessed Patellar Component has been cleared for marketing in two thicknesses (8mm and 10mm), and five diameters (25mm, 27mm, 29mm, 31mm, and 35mm).

Testing was presented to support the claim of substantial equivalence.

For further information contact:
Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401
(201) 934-4359 (Telephone)
(201) 760-8435 (Fax)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 6 2002

Ms. Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route17
Allendale, New Jersey 07041

Re: K020830
Trade/Device Name: Scorpio® Inset Patellar Component
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: March 13, 2002
Received: March 14, 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,

for Mark N Melkerson

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

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INDICATIONS FOR USE

510(k) Number (if known): K020830

Device Name: Scorpio® Inset Patellar Component

Indications for Use:

The Scorpio® Inset Patellar Component is intended to articulate with any commercially available Scorpio® Total Knee Femoral Component, ,any commercially available Osteonics® Series 7000 Total Knee Femoral component, and any commercially available Osteonics® Omnifit® Total Knee Femoral Component. The subject patellar components are single use devices, intended for cemented applications on the surgically prepared posterior patella as part of primary or revision total knee arthroplasty. This component replaces the patellar articulating surface of the knee joint to simulate the normal function 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)

(Optional Format 1-2-96)

for Mark N Milhous

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

510(k) Number K020830