MAY 17 [illegible] K991961

Special 510(k) - Device Modification
Summary of Safety and Effectiveness for the
Osteonics® Scorpio™ Total Knee Relaxed Back P/S Tibial Bearing Insert

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:	Marybeth Naughton Regulatory Affairs Team Member
Date of Summary Preparation:	April 16, 1999

Device Identification

Proprietary Name:	Osteonics® Scorpio™ Total Knee Relaxed Back P/S Tibial Bearing Insert
Common Name:	Knee Prosthesis
Classification Name and Reference:	Knee Joint, Patellofemorotibial, Polymer/Metal/Polymer, Semi-Constrained, Cemented Prosthesis 21 CFR §888.3560

Predicate Device Identification

The modified features of the Osteonics® Scorpio™ Total Knee Relaxed Back P/S Tibial Bearing Inserts are substantially equivalent to features of the following Osteonics® predicate device, which has been cleared for marketing via the 510(k) process:

- Osteonics® Scorpio™ Total Knee Posteriorly Stabilized Tibial Bearing Insert (#K962152)

Device Description

The Osteonics® Scorpio™ Total Knee Relaxed Back P/S Tibial Bearing Insert is a modification of the predicate Osteonics® Scorpio™ Total Knee Posteriorly Stabilized Tibial Bearing Insert.

The modification involves increasing the posterior radius of the tibial bearing insert to a value of six inches as compared to three inches for the standard Scorpio™ family of tibial bearing inserts. This modification is designed to allow the femur to reach deeper flexion angles by further resisting femoro-tibial distraction and increase ligament tension in the deep flexion range. All other design features of the modified Scorpio™ design tibial bearing insert will remain unchanged. The sizes and UHMWPE thicknesses of the modified tibial bearing inserts will be identical to the predicate tibial bearing insert design.

Intended Use:

The intended use of the modified tibial bearing inserts is identical to that of the unmodified tibial bearing inserts. As with the predicate tibial bearing inserts, the modified tibial bearing inserts are single use devices. They are intended for mating with commercially available Osteonics® Tibial Trays and corresponding posteriorly stabilized femoral and patellar components. The Osteonics® Scorpio™ Posteriorly Stabilized Total Knee Components are intended for cemented fixation. Specific indications for use are as follows:

- 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.

Performance Data:

A Risk Analysis and R & D Testing have have been performed to demonstrate the substantial equivalence of this tibial bearing insert design to the predicate tibial bearing insert design.

Statement of Technological Comparison:

All features of the Osteonics® Scorpio™ Total Knee Relaxed Back P/S Tibial Bearing Insert are unchanged with the exception of 1) the change posterior radius of the tibial bearing insert from three inches to six inches. All other design features, materials and manufacturing methods will remain unchanged.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 1999

Ms. Marybeth Naughton
Regulatory Affairs
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K991461
Osteonics® Scorpio™ Total Knee Relaxed Back P/S Tibial Bearing Insert
Regulatory Class: II
Product Code: JWH
Dated: April 22, 1999
Received: April 27, 1999

Dear Ms. Naughton:

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). This decision is based on this device system being equivalent only to similar device systems labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. The thinnest tibial insert available is the nominal "size 3" insert, which has a minimum polyethylene thickness under the condyles of 6.25mm.

2. This device system may not be labeled or promoted for non-cemented use.

3. All labeling for this device system, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

4. Any non-cemented fixation of this device system is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device system for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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 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 (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): K991461

Device Name: Osteonics® Scorpio™ Total Knee Relaxed Back P/S Tibial Bearing Insert

Indications For Use:

The indications for the use of the Osteonics® Scorpio™ Total Knee Relaxed Back P/S Tibial Bearing Insert , in keeping with those of other legally marketed Osteonics® total knee 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.
- 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)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991461