FEB 2 7 1998

K974556

510(K) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
OSTEONICS® SCORPIO™ POSTERIOR CRUCIATE RETAINING TOTAL KNEE SYSTEM

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677
201-825-4900

Contact Person:

Donna S. Wilson
Regulatory Affairs Specialist

Date Summary Prepared:

December 4, 1997

Device Identification

Proprietary Name:

Osteonics® Scorpio™ Posterior Cruciate Retaining Total Knee System

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 Osteonics® Scorpio™ Total Knee CR Femoral Components are substantially equivalent to both the Osteonics® Scorpio™ Total Knee Posteriorly Stabilized Femoral Components, and the Osteonics® Series 7000 Total Knee Femoral Components. The Osteonics® Scorpio™ Total Knee CR All-Polyethylene Tibial Components are substantially equivalent to the Osteonics® Series 7000 Total Knee All-Polyethylene Tibial Components. The Osteonics® Scorpio™ Total Knee CR Tibial Bearing Inserts are substantially equivalent to the Osteonics® Tibial Bearing Inserts.

Device Description

Osteonics® Scorpio™ Total Knee Posterior Cruciate Retaining Femoral Components: The Osteonics® Scorpio™ Total Knee Posterior Cruciate Retaining (CR) Femoral Components are fabricated from cobalt chromium alloy, available in right and left configurations, with or without two interior fixation lugs, and are available with three different interior surface textures to supplement the cement fixation of the device: basic grit-blasted surface roughness, waffle pattern, and

MicroStructured® porous coating. These femoral components achieve primary fixation by interdigitation of the PMMA bone cement with the surface texture and the apposing bone.

Osteonics® Scorpio™ Total Knee Posterior Cruciate Retaining All-Polyethylene Tibial Components: The Osteonics® Scorpio™ Total Knee Posterior Cruciate Retaining (CR) All-Polyethylene Tibial Components are one-piece total knee replacement tibial components, fabricated from ultra-high molecular weight polyethylene (UHMWPE). The bearing surface of the Osteonics® Scorpio™ Total Knee CR All-Polyethylene Tibial Components employ a single M/L radius. A radiographic locator wire is positioned in the distal end of the post and in the inferior/anterior side of the tray. The Osteonics® Scorpio™ Total Knee CR All-Polyethylene Tibial Components are intended for cemented fixation. Primary fixation is to be achieved through interface of the bone cement with the tibial post, which is of the swept back, keeled design.

Osteonics® Scorpio™ Total Knee Posterior Cruciate Retaining Tibial Bearing Inserts: The Osteonics® Scorpio™ Total Knee Posterior Cruciate Retaining (CR) Tibial Bearing Inserts are fabricated from ultra-high molecular weight polyethylene (UHMWPE). These tibial bearing inserts are assembled to the appropriate tibial tray intraoperatively via a locking wire mechanism. The bearing surface of the Osteonics® Scorpio™ Total Knee CR Tibial Bearing Inserts employ a single M/L radius, and accommodate the bearing geometry of the Osteonics® Scorpio™ Total Knee CR Femoral Components. The Osteonics® Scorpio™ Total Knee CR Tibial Bearing Inserts are intended for femoro-tibial articulation with the Osteonics® Scorpio™ Total Knee CR Femoral Components. This tibial bearing insert is designed to be assembled with the Osteonics® Series 7000 Total Knee Tibial Trays or the Osteonics® Omnifit® Total Knee Tibial Trays.

Intended Use

These devices are single use components, intended for cemented fixation, and indicated for use in total knee replacement in conjunction with an Osteonics® Scorpio™ Patellar Component, when the posterior cruciate ligament is functional. The indications for use of the Osteonics® Scorpio™ Posterior Cruciate Retaining Total Knee System 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.

Statement of Technological Comparison

The Osteonics® Scorpio™ Posterior Cruciate Retaining Total Knee System components share the same materials, intended use, and basic design features of their respective predicate devices. Applicable performance testing demonstrates that the subject components perform at least as well as, if not better than, the predicate commercially available designs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 1998

Ms. Donna S. Wilson
Regulatory Affairs Specialist
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K974556
Osteonics Scorpio Posterior Cruciate Retaining
Total Knee System
Regulatory Class: II
Product Code: JWH
Dated: December 4, 1997
Received: December 5, 1997

Dear Ms. Wilson:

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 being equivalent only to similar devices 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. This device may not be labeled or promoted for non-cemented use.

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

3. Any non-cemented fixation of this device 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 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,

for 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): K974556

Device Name: Osteonics® Scorpio™ Posterior Cruciate Retaining Total Knee System

Indications For Use:
The Osteonics® Scorpio™ Posterior Cruciate Retaining (CR) Total Knee System consists of posterior cruciate retaining total knee replacement femoral components, with corresponding cruciate retaining tibial bearing components, specifically designed to articulate together. These devices are single use components, intended for cemented fixation, and indicated for use in total knee replacement when the posterior cruciate ligament is functional.

The Osteonics® Scorpio™ Total Knee CR Femoral Components are compatible for femoro-tibial articulation with the Osteonics® Scorpio™ Total Knee CR Tibial Bearing Inserts and the Osteonics® Scorpio™ Total Knee CR All-Polyethylene Tibial Components. The Osteonics® Scorpio™ Total Knee CR Tibial Bearing Inserts are intended for use with the legally marketed Osteonics® Series 7000 Total Knee Tibial Trays and Osteonics® Omnifit® Total Knee Tibial Trays.

The Osteonics® Scorpio™ Total Knee CR Femoral Components are intended for patello-femoral articulation with the Osteonics® Scorpio™ Total Knee Patellar Components. In addition, the Osteonics® Series 7000 Femoral Bone Augmentation Components are compatible with the Osteonics® Scorpio™ Total Knee CR Femoral Components.

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.

(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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974556

~~(Optional~~ Format 1-2-96)