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Osteonics® Scorpio Posteriorly Stabilized Total Knee System

510(k) Premarket Notification

K962152

**510(K) PREMARKET NOTIFICATION  
SUMMARY OF SAFETY AND EFFECTIVENESS  
OSTEONICS® SCORPIO POSTERIORLY STABILIZED 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:**

June 3, 1996

**Device Identification**

**Proprietary Name:**

Osteonics® Scorpio Posteriorly Stabilized  
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**

Osteonics® Scorpio Total Knee Posteriorly Stabilized Femoral Components are substantially equivalent to the Osteonics® Series 7000 Total Knee Primary Posteriorly Stabilized Femoral Components. The Osteonics® Scorpio Total Knee Posteriorly Stabilized All-Polyethylene Tibial Component is substantially equivalent to the Osteonics® Series 7000 Total Knee Primary Posteriorly Stabilized All-Polyethylene Tibial Component. The Osteonics® Scorpio Total Knee Posteriorly Stabilized Tibial Bearing Insert is substantially equivalent to the Osteonics® Series 7000 Total Knee Tibial Bearing Insert - P/S I Series. The Osteonics® Scorpio Total Knee All-Polyethylene Patellar Components are substantially equivalent to the Osteonics® Series 7000 Total Knee Resurfacing Patellar Components.

## **Device Description**

### **Osteonics® Scorpio Total Knee Posteriorly Stabilized Femoral Components**

The Osteonics® Scorpio Total Knee Posteriorly Stabilized Femoral Components are fabricated from cobalt chromium alloy, and are intended for cemented application to replace the articulating surface of the distal femur. These posteriorly stabilized femoral components are utilized when total knee replacement is indicated, and the posterior cruciate ligament is non-functioning or absent, resulting in joint instability.

The Osteonics® Scorpio Total Knee Posteriorly Stabilized Femoral Components are available in right and left configurations, and 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. The Osteonics® Scorpio Total Knee Posteriorly Stabilized Femoral Components are available either with or without nitrogen ion implanted bearing surfaces.

### **Osteonics® Scorpio Total Knee Posteriorly Stabilized All-Polyethylene Tibial Component**

The Osteonics® Scorpio Total Knee Posteriorly Stabilized All-Polyethylene Tibial Component is a one-piece total knee replacement tibial component, fabricated from ultra-high molecular weight polyethylene (UHMWPE). The Osteonics® Scorpio Total Knee Posteriorly Stabilized All-Polyethylene Tibial Component, when used in conjunction with its mating Osteonics® Scorpio Total Knee Posteriorly Stabilized Femoral Component, provides the constraint needed to compensate for an absent or incompetent posterior cruciate ligament.

The bearing surface of the Osteonics® Scorpio Total Knee Posteriorly Stabilized All-Polyethylene Tibial Component employs a single medial lateral (M/L) radius, and incorporates a posteriorly sloping, raised tibial eminence, a radiographic locator wire, and a swept back, keeled post. The Osteonics® Scorpio Total Knee Posteriorly Stabilized All-Polyethylene Tibial Component is intended for cemented fixation. Primary fixation is to be achieved through interface of the bone cement with the tibial post.

### **Osteonics® Scorpio Total Knee Posteriorly Stabilized Tibial Bearing Insert**

The Osteonics® Scorpio Total Knee Posteriorly Stabilized Tibial Bearing Insert is fabricated from ultra-high molecular weight polyethylene (UHMWPE). This tibial bearing insert is assembled to the tibial tray component intraoperatively via a locking wire mechanism.

The articulating surface area of the Osteonics® Scorpio Total Knee Posteriorly Stabilized Tibial Bearing Insert is identical to that of the Osteonics® Scorpio Total Knee Posteriorly Stabilized All-Polyethylene Tibial Component.

### **Osteonics® Scorpio Total Knee All-Polyethylene Patellar Components**

The Osteonics® Scorpio Total Knee All-Polyethylene Patellar Components are fabricated from ultra-high molecular weight polyethylene (UHMWPE), and are intended for cemented application

onto the surgically prepared posterior patella. They replace the patellar articulating surface of the knee joint and simulate the natural anatomy and function of the knee.

The articular geometry is designed with a single medial lateral (M/L) radius. The overall geometry essentially consists of an oval patellar button configuration with three fixation pegs in the anterior surface of the component. The Osteonics® Scorpio Total Knee All-Polyethylene Patellar Components are available in three design configurations - Concentric Dome, Medialized Dome, and Superior-Medialized Dome.

### **Intended Use**

The indications for the use of these posteriorly stabilized total knee components, in keeping with those of other legally marketed Class II posteriorly stabilized 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.

### **Statement of Technological Comparison**

The Osteonics® Scorpio Posteriorly Stabilized Total Knee System components share the same materials, indications and intended use, surgical techniques, basic design features, and basic manufacturing methods of their respective predicate devices. These components are substantially equivalent to predicate devices by virtue of providing for cemented application of the femoral, patellar, and all-polyethylene tibial components, security of fixation, proper load transfer, and a biomechanical function and range of motion which approximate the normal knee when used in conjunction with each other and/or the associated Osteonics® Series 7000 Total Knee Tibial Trays and Osteonics® Omnifit Total Knee Tibial Trays, as applicable. Although the articulating surfaces of the subject devices differ slightly from that of their predicate devices, applicable performance testing demonstrates that no significant difference exists between these components and their predicate designs.