MAR - 6 2000

K994128

510(k) Summary
Scorpio® Total Stabilizer (TS) Total Knee System

Submission Information

Name and Address of the Sponsor:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Terry Sheridan Powell
Date of Summary Preparation:	December 3, 1999

Device Identification

Proprietary Name:	Scorpio® Total Stabilizer (TS) Total Knee System
Common Name:	Artificial Total Knee Replacement System
Classification Name and Reference:	CFR §888.3353

Predicate Device Identification

The subject devices are substantially equivalent to the following competitive and/or Osteonics devices, which have previously been determined substantially equivalent by FDA:

- K962152: Scorpio® Posteriorly Stabilized (PS) Total Knee System Femoral, Tibial Insert, and Patellar Components (sponsor: Osteonics)
- K974566: Scorpio® Cruciate Retaining (CR) Total Knee System Femoral and Tibial Insert components (sponsor: Osteonics)
- K972967: Scorpio® Total Knee Universal Dome and Recessed Patellar Components (sponsor: Osteonics)
- K915192: 7000 Series Total Knee Modular Tibial Component (sponsor: Osteonics)
- K925372: 7000 Series Total Knee Modular Femoral Component (sponsor: Osteonics)
- K920524: Osteonics Series 7000 Total Knee Tibial and Femoral Augmentation Blocks and Wedges (sponsor: Osteonics)
- K960279: Legacy Constrained Condylar Knee (CCK) (sponsor: Zimmer)

Device Description

The Scorpio® TS Total Knee System consists of new femoral components, tibial trays, tibial inserts, and femoral and tibial augmentation. The system will be used in conjunction with existing, predicate patellar components, tibial tray screws, femoral and tibial stem extensions, and femoral and tibial stem extension offset adaptors.

Femoral Components:
The Scorpio® TS Total Knee System Femoral Components share many of the design features originally featured in the predicate Scorpio® Posteriorly Stabilized Total Knee System Femoral Components. The subject components, however, have been modified to address the revision and femoral TS situations discussed in the Indications section of this submission. Briefly, the modifications involve closing the cam box (to facilitate use with more constraining tibial insert configurations), providing an attachment mechanism for femoral stem extension and offset adaptor attachments, and providing attachment mechanisms/surfaces for new bone augmentation components.

Tibial Trays:
There are two tibial tray styles for the Scorpio® TS Total Knee System: non-ported and ported. Each is available with one of three surfaces on the underside of the tray designed to improve the cement-component interface: the basic, grit-blasted surface roughening, the cast-in waffle pattern, or the MicroStructured® porous coating. The tibial trays features screw holes for optional use with bone screws for supplemental fixation, or for optional use with bone augment components (attached to the tray with screws). If supplemental tibial bone screws are used, then tibial bone augments cannot be used (because both require the same screw holes), and vice versa. The trays are compatible with subject Scorpio® TS Inserts, or with predicate Scorpio® PS or CR Inserts.

Non-ported Style
The non-ported style tibial tray is nearly identical to the predicate Osteonics® Series 7000 Total Knee Tibial Trays, differing only slightly in the configuration of the central post. The central post on the predicate trays extends beyond the swept-back fins of the delta-fit keel. The central post of the new, subject trays is slightly shortened so that it is nearly flush with the bottom of the keel. The threads at the distal end of the post have also been modified to accept the predicate Howmedica Duracon® Total Stabilizer (TS) Extension Stems and Offset Adaptors.

Ported Style
The ported-style trays are identical in design to the non-ported style trays, except with a hole in the A/P direction through the central post of the keel. This hole allows a two-step cement procedure to fill and pressurize the metaphyseal region around the keel. The technique consists of:

1) cementing on the tibial tray with cement only on the periphery of the tray, and allowing the cement to harden (cure),
2) injecting cement through the port hole in the central post until the metaphyseal region is pressurized (felt as resistance against cement gun).

Pressurization of the metaphyseal region may benefit the cement/bone interface.

Tibial Inserts:
The Scorpio® TS Total Knee System Tibial Inserts feature a raised tibial eminence with an interior reinforcing pin that is slip-fit into the tibial tray. This insert provides anterior/posterior constraint as well as varus/valgus constraint. It is similar in constraint level to the predicate Zimmer Legacy Constrained Condylar Knee (LCCK).

In keeping with the design theory behind the predicate Osteonics tibial inserts, the bearing surface of the subject inserts employs a single medial lateral (M/L) radius. The bearing surface also incorporates a posteriorly sloping, raised tibial eminence. The inserts come in a range of thicknesses. They feature the same locking mechanism as the predicate Scorpio® Inserts, and the same articulating geometry as the predicate Scorpio® CR Inserts.

Femoral Augmentation:
Distal femoral augmentation is available in 5mm, 10mm, and 15mm thicknesses. Posterior femoral augmentation is available in 5mm, 10mm, and 15mm thicknesses. These augment pieces are attached with a hex-head screw to the subject Scorpio® TS Femoral Components. They are compatible with the predicate PS or CR Scorpio® Femoral Components, but must be affixed via bone cement (not through screw fixation) to those predicate devices.

Tibial Augmentation:
Tibial augmentation is available in the following configurations:

- Half blocks for medial or lateral coverage in 5mm or 10mm thicknesses.
- Full coverage blocks 10mm thick.
- Full coverage 5° wedges, which can be flipped to accommodate a medial or lateral deficiency.

The wedges are attached to the trays with bone cement. The blocks are attached to the trays by placing one or more screws (depending on the type of augment) through the tray and threading them into the augments. The augments feature a cement recess pocket.

Intended Use:
The Scorpio® TS Total Knee System components are intended for single-use, and are labeled for cemented use only in the United States. The components feature a posterior cruciate ligament (PCL) substituting design. This system is intended for use when the cruciate ligaments are absent, inadequate, or cannot be preserved during the operative procedure, especially when anterior-posterior stability is impaired due to the absence of the posterior cruciate ligament and/or patella. The collateral ligaments may or may not be intact. The system is also designed to

allow compensation for bone loss through the use of blocks and/or wedges.

General TKR 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.

Additional Indications for Posterior Stabilized (PS) or Total Stabilized (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.
- **For Total Stabilizer (TS) Components Only**: Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augmentation Wedges:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Statement of Technological Comparison:

The substantial equivalence of the subject device is supported by a comparison of the subject device to the above-cited predicate devices. A comparison of the subject and predicate devices in terms of intended use, materials, and design follows.

Intended Use

The Scorpio® TS Total Knee System components share the same intended uses as the predicate Osteonics Series 7000 Modular Tibial and Femoral Knee System Components.

Materials

The Scorpio® TS Total Knee System components are manufactured from UHMWPE and CoCr alloys. These materials have been commonly used in the manufacture of total knee systems for decades, and are the same materials used in the manufacture of the predicate knee systems.

Design

The subject femoral components are basically a blend between the predicate Scorpio® PS Femoral components and the predicate Series 7000 Modular Femoral component. The subject femoral components incorporate the epicondylar-based center of rotation featured on the predicate Scorpio® PS Femoral components, and the box-style housing (to allow attachment of

stem extensions and additional constraint) featured on the predicate Series 7000 Modular Femoral components.

The subject tibial trays, which come in non-ported and ported styles, are a modification to the predicate 7000 Series Total Knee Modular Tibial Components. The main difference is the central post. The subject trays feature a central post which has been slightly shortened so that it is nearly flush with the bottom of the swept-back keel. In addition, the ported-style tray differs in that it features a cement port, to allow pressurization of the cement in the metaphyseal region.

The tibial inserts feature a reinforcing pin that is slip-fit into the tibial tray (same reinforcing pin determined substantially equivalent via K915192). They are similar in constraint level to the predicate Zimmer Legacy Constrained Condylar Knee (LCCK).

The subject augment components do not differ significantly in configuration (distal and posterior femoral augments, half and full tibial block augments, and tibial wedges) or in thickness or angle from existing predicate augment systems.

Summary
The subject Scorpio® TS Total Knee System does not feature any new materials or intended uses. The subject system does feature some new design variations; however, these are modest design differences which do not raise new issues of safety or effectiveness when compared to the predicate devices, and whose substantial equivalence is further supported by the performance testing provided within the document.

Performance Data:
This submission includes testing of the new mechanism for attachment of the augmentation components. This testing showed that the mechanism featured on the new subject augment components is at least as strong as the mechanism featured on predicate augment systems. This submission also includes fatigue testing of the ported-style tibial trays, which demonstrates that these trays are at least as strong as other, commercially-available tibial trays.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2000

Ms. Terry Sheridan Powell
Regulatory Affairs Team
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K994128
Trade Name: Scorpio® Total Stabilizer (TS) Total Knee System
Regulatory Class: II
Product Code: JWH
Dated: December 3, 1999
Received: December 7, 1999

Dear Ms. Sheridan Powell:

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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (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. 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 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K994128

Device Name: Scorpio® Total Stabilizer (TS) Total Knee System

The Scorpio® TS Total Knee System components are intended for single-use, and for cemented use only in the United States. The components feature a posterior cruciate ligament (PCL) substituting design. This system is intended for use when the cruciate ligaments are absent, inadequate, or cannot be preserved during the operative procedure, especially when anterior-posterior stability is impaired due to the absence of the posterior cruciate ligament and/or patella. The collateral ligaments may or may not be intact. The system is also designed to allow compensation for bone loss through the use of blocks and wedges.

General TKR 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.

Additional Indications for Posterior Stabilized (PS) or Total Stabilized (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.
- **For Total Stabilizer (TS) Components Only**: Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augmentation Wedges:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

NRO for JZD

(Division Sign-Off)
Division of General Restorative Devices K994128
510(k) Number _____

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

(Optional Format 1-2-96)