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AUG 23 2012

510(k) Summary
POLARCUP® Dual Mobility System

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Summary:	July 26, 2012
Contact Person	John Connor, Regulatory Affairs Specialist T (901) 399-5944 F (901) 566-7961
Name of Device:	POLARCUP® Dual Mobility System
Common Name:	Acetabular Component
Device Classification Name and Reference:	21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis. 21 CFR 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis.
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	LPH, KWY, JDI

Device Description
The POLARCUP® Dual Mobility System consists of a metal shell and plastic liner (or insert). The inside of the metal shell is polished, and the outside of the plastic liner is able to articulate against this polished surface. This dual mobility design results in higher intra-prosthetic stability to address the treatment of patients with a high risk of dislocation (especially for elderly patients) or patients with recurrent dislocation. The subject of this premarket notification is the addition of an outer hydroxylapatite coating to the currently available acetabular shell.

Intended Use
The POLARCUP® Dual Mobility System is indicated for:

- Advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis.
- Fracture or avascular necrosis of the femoral head

- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement
- All forms of osteoarthritis
- Patients with hips at risk of dislocation
- Femoral neck fracture or proximal fracture to hip joint

The titanium plasma and titanium/HA coated implants are intended to be implanted without bone cement. The uncoated implant is intended to be implanted with bone cement. The POLARCUP® Dual Mobility System is intended for single use only.

Technological Characteristics
A review of the mechanical data indicates that the POLARCUP® Dual Mobility System is capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information
The overall design, materials, and indications for use for the POLARCUP® Dual Mobility System are substantially equivalent to the following commercially available predicate devices.

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew Orthopaedics AG	SL-PLUS® Standard and Lateral Femoral Stems	K120211	7/19/12
Smith & Nephew Orthopaedics AG	POLARCUP® Dual Mobility System	K110135	10/14/11

All tests which are in relation to the surface characterization (physical, chemical or mechanical) are discussed in detail in the Ti/HA Coating Master File **MAF – 1762, Amendment 1** and are not included in this dossier.

Conclusion
As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for the POLARCUP® Dual Mobility System. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to the commercially available predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Incorporated
% Mr. John Connor
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

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Re: K122244
Trade/Device Name: POLARCUP◊ Dual Mobility Systems
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, KWY, JDI
Dated: July 26, 2012
Received: July 27, 2012

Dear Mr. Connor:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K122244

Device Name: POLARCUP® Dual Mobility System

Indications for Use:

The POLARCUP® Dual Mobility System is indicated for:

- Advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis.
- Fracture or avascular necrosis of the femoral head
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement
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Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122244