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510(k) Summary of Safety and Effectiveness

Submitted by:	United Orthopedic Corporation
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Date of Summary:	June 01 , 2011
Contact Person:	Fang-Yuan Ho Manager, Regulatory Affairs
Proprietary Name:	U2 Hip System
Common Name:	Semi-constrained total hip prostheses
Device Classification Name and Reference:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis under 21CFR 888.3358 This falls under the Orthopedics panel.
Device Class	Class II
Panel Code	Orthopaedics Device
Device Product Code:	LPH, JDI
Predicate Device:	1. "Smith & Nephew" R3 Acetabular Cup System (K070756) 2. "UNITED" Femoral Head (K022520, K994078) 3. "Osteonics" Crossfire System Acetabular Insert (K993352) 4. "Smith & Nephew" Synergy Hip System-Press Fit (K061066) 5. "Smith & Nephew" Synergy Cemented Hip Stem (K990369) 6. "Zimmer" Intramedullary Bone Plug (K001733)

Device Description:

U2 Hip System designed for hip arthroplasty is a metal/polymer/metal

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semi-constrained prosthesis with femoral components and acetabular components. The femoral components are composed of a ball mechanical locked with a stem by means of a Morse taper, while the acetabular components are composed of an highly crosslinked ultra – high – molecular – weight - polyethylene articulating bearing surface fixed in a metal shell. Components of this premarket notification include the following components:

- Ti Porous Coated Cup
- XPE Cup Liner
- 32 mm and 36 mm Femoral Head
- U2 Hip Stem, Press-fit
- U2 Hip Stem, Cemented

The titanium bar (ASTM F136) was forged into a net-shape of acetabular cup and then the forged part was machined into the final shape of Ti Porous Coated Cup. The outer surface is porous coated with three layers of CP Ti beads (ASTM F1580). XPE Cup Liner is manufactured from highly crosslinked UHMWPE which conform to ASTM F2565 and the UHMWPE raw material is in accordance with ASTM F648 and ISO 5834. The first series of XPE Cup Liner with the sizes of 44 to 80 mm has an inner diameter of 28 mm. The second series with the sizes of 50 to 80 mm have an inner diameter of 32 mm. The third series with the sizes from 54 to 80 mm have an inner diameter of 36 mm. The 32 and 36 mm Femoral Head is manufactured from CoCrMo alloy (ASTM F1537) with neck length of –3, +0, +5, and +10 mm. U2 Press-fit Stem is manufactured from titanium alloy (ASTM F620) which is intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty. U2 Cemented Hip Stem manufactured from forging CoCrMo alloy (ASTM F799) is intended for cement fixation. Moreover, this device is available to use with an accessory, called "Cement Restrictor, Full PE" made of Ultra-High Molecular Weight Polyethylene (ASTM F648).

The Ti Porous Coated Cup will be used with 510k cleared cup liner of the U2 Acetabular

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Component (K050262) and currently submission XPE Cup Liner. As using with the existing cup liner (K050262), the Ti Porous Coated Cup may be used with 26 mm and 28 mm Femoral Head (K994078 and K022520) and 28 mm Ceramic Femoral Head (K103479). As using with currently submission XPE Cup Liner, this component may be used with currently submission 32 mm and 36mm Femoral Head, the 28 mm Femoral Head (K022520) and 28 mm and 32 mm Ceramic Femoral Head (K103479). Besides, XPE Cup Liner may also be used with existing U2 Acetabular Cup (K050262). The 32 mm and 36 mm Femoral Head may also be used with U2 Bipolar Implant (K101670), Revision Stem (K062978) and current submission Cemented Stem and Press-fit Stem

The Press-fit Stem and Cemented Stem will be used with currently submission 32mm and 36 mm metal Femoral Head and may be used with 26 mm and 28 mm metal Femoral Head (K994078 and K022520). The Press-fit Stem which made from Ti alloy can also be used with Ceramic Femoral Head (K103479).

Indications for Use:

This device is indicated in hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

For use as a Total Hip Replacement

1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For use as a Bipolar Hip Replacement

1. Femoral head/neck factures or non-unions.
2. Aseptic necrosis of the femoral head.

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3. Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Cemented stem is designed for cemented use only.

Basis for Substantial Equivalence:

The substantial equivalence of the U2 Hip System is based on its similarities in indications for use, design features, operational principles, and material composition to the predicate systems listed in the table below.

Current Subject	Predicate Systems	Manufacture	Submission Number	Decision Date
Ti Porous Cup	R3 ACETABULAR CUP SYSTEM	Smith & Nephew, Inc.	K070756	06/06/2007
XPE Cup Liner	Crossfire System Acetabular Insert	Osteonics	K993352	11/19/1999
32mm and 36 mm Femoral Head	26mm Femoral Head	United Orthopedic Co.	K022520	02/25/2003
	28mm Femoral Head	United Orthopedic Co.	K994078	12/04/2000
Press-fit Stem	SYNERGY HIP SYSTEM-Press Fit Stem	Smith & Nephew, Inc.	K061066	07/14/2006
Cemented Stem	Synergy Cemented Hip Stem	Smith & Nephew, Inc.	K990369	03/12/1999
Cement Restrictor for Cemented Stem	Intramedullary Bone Plug	Zimmer	K001733	06/20/2000

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Performance Test – Bench:

This 5101k) was prepared in accordance with the Agency's, " Class II Special Controls Guidance Document- Hip Joint Metal Polymer Constrained Cemented or Uncemented Prosthesis", "Guidance for Non-clinical Information for Femoral Stem Prostheses", "Guidance Document for Testing Non-Articulating, 'Mechanically Locked', Modular Implant Components" and "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement". A review of the mechanical data indicates that the U2 Hip System is capable of withstanding expected *in vivo* loading without failure. The following mechanical tests of the U2 Hip System were performed:

- Locking Strength of XPE Cup Liner per ASTM F1820
- Wear Simulation Test of XPE Cup Liner per ISO 14242-1
- Range of Motion for XPE Cup Liner and 32 and 36 mm Femoral Head by CAD simulation
- Femoral Head Disassembly loads for the Subject Stem per ASTM F2009
- Stem Fatigue Test for Press-fit Stem and Cemented Stem with Torsion per ISO 7206-4 and ASTM F1612
- Neck Fatigue Test for Press-fit Stem and Cemented Stem with Torsion per ISO 7206-6
- Evaluation of modified surface treatment includes SEM evaluation per ASTM F1854, shear fatigue testing per ASTM F1160, static shear testing per ASTM F1044, static tensile testing per ASTM F1147, and taber abrasion resistance per ASTM F1978
- Characterize of material properties of XPE cup liner includes tensile properties per ASTM D638, ultimate load per ASTM F2183, Izod impact strength per ASTM F648, Annex 1, fatigue crack propagation per ASTM E647, thermal properties (i.e. % crystallinity and melting temperature) per ASTM D3418, residual free radicals via ESR, swell ratio per ASTM F2214, oxidation index (OI) per ASTM F2102,

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and trans-vinylene index (TVI) per ASTM F2381.

A review of these tests has demonstrated that there are no new issues related to the safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the U2 Hip System. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to predicate hip systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Silver Spring, MD 20993-0002

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Re: K111546
Trade Name: U2 Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI
Dated: June 1, 2011
Received: June 3, 2011

Dear Fang-Yuan Ho:

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

Indication for Use

510 (k) Number (if known): K111546

Device Name: U2 Hip System

Indications for Use:

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Cemented stem is designed for cemented use only.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

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

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