

K121777

JUL 18 2012

 U2 Acetabular Cup, Plasma Spray

510(k) Summary

### 510(k) Summary of Safety and Effectiveness

**Submitted by:** United Orthopedic Corporation  
**Address:** No 57, Park Ave 2, Science Park, Hsinchu 300, Taiwan  
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**Fax Number:** +886-3-5777156  
**Date of Summary:** June 15, 2012  
**Contact Person:** Fang-Yuan Ho  
Regulation and Document Management  
**Proprietary Name:** U2 Acetabular Cup, Plasma Spray  
**Common Name:** Hip Prosthesis  
**Device Classification:** Hip joint metal/polymer/metal semi-constrained porous-coated  
**Name and Reference:** uncemented prosthesis per 21CFR 888.3358  
This falls under the Orthopedics panel.  
**Device Class:** Class II  
**Panel Code:** Orthopaedics Device  
**Device Product Code:** LPH, MEH  
**Predicate Device:**  

1. "United" U2 Acetabular Component (K050262)
2. "ENCORE MEDICAL, L.P." FMP Acetabular Shell (K063257)
3. "Depuy" Pinnacle<sup>®</sup> Duofix<sup>®</sup> HA Shells (K031495)
4. "BIOMET<sup>®</sup>" Universal<sup>®</sup> Acetabular Component (K921301)

#### **Device Description:**

"UNITED" U2 Acetabular Cup - Plasma Spray is an extension of cleared "UNITED" U2 Acetabular Component (K050262). The materials, safety and effectiveness of this

subject are identical to the previously cleared U2 Acetabular Cup (K050262), except for adding sizes and multi-hole cup design. The extension of each coating type is described as following:

1. U2 Acetabular Cup – Ti Plasma Spray Coating: This submitted device adds the clustered-hole and multi-hole designs in sizes 44 ~ 80 mm and extends the size of no-hole design to #80. The catalog numbers of the cleared no-hole design are shifted to be used by clustered-hole, and the no-hole design is given new catalog numbers and extends its size to # 80. They are coated with CP Ti powder (ASTM F1580) to form a rough surface.
2. U2 Acetabular Cup -- HA/Ti plasma spray Coating: This submitted device extends cup size to #80 and increase the no-hole and multi-hole cup design for alternative. They are coated with dual coatings, which are CP Ti powder (ASTM F1580) for the inner layer and HA (ASTM F1185) for the outer layer.

This device is intended to be used with the previously cleared U2 Acetabular cup liner (K050262), U2 XPE liner (K111546), "UNITED" Femoral head (K994078, K022520), "United" Ceramic Femoral Head (K103497, K112463) and Titanium cancellous bone screw (K050262) in corresponding size. The modifications of Acetabular cup do not affect the intended use of the device or alter the fundamental scientific technology of the device.

### **Intended Use**

The devise is used for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. Inflammatory degenerative joint disease such as rheumatoid arthritis;

3. Correction of function deformity;
4. Revision procedures where other treatments or devices have failed; and
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that is unmanageable using other techniques.

The device is intended for uncemented use and is single use only.

This is the **same intended use** as previously cleared for **“UNITED” U2 Acetabular Component, K050262**.

**Basis for Substantial Equivalence:**

The safety and effectiveness of this device are substantially equivalent to previously cleared U2 Acetabular Component (K050262), except for an extension in size distribution and for an increase of multi-hole cup design. The modifications do not change the intended use or fundamental scientific technology. In addition, the subject device is also substantial equivalence to the Predicate-“ENCORE MEDICAL, L.P.” FMP Acetabular Shell (K063257), “Depuy” Pinnacle<sup>®</sup> Duofix<sup>®</sup> HA Shells (K031495) and “BIOMET<sup>®</sup>” Universal<sup>®</sup> Acetabular Component (K921301).

**Performance Data:**

The mechanical properties of the modified surface have been evaluated to conform to FDA guidance: “*Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; Guidance for Industry and FDA*”. And the locking strength test completed as part of the design assurance process, demonstrated that this device is safe and effective and is substantially equivalent to the predicate device.



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

United Orthopedic Corporation  
% Ms. Fang-Yuan Ho  
Regulatory Affairs Manager  
No. 57 Park Ave 2 Science Park  
Hsinchu 300 Taiwan

JUL 18 2012

Re: K121777

Trade/Device Name: U2 Acetabular Cup, Plasma Spray  
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, MEH  
Dated: June 15, 2012  
Received: June 18, 2012

Dear Ms. 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

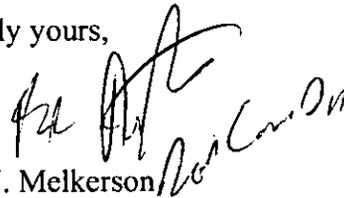
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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing 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/ucml15809.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): K121777

Device Name: Acetabular Cup, Plasma Spray

### Indications for Use:

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

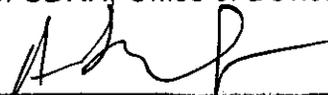
1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. Inflammatory degenerative joint disease such as rheumatoid arthritis;
3. Correction of function deformity;
4. Revision procedures where other treatments or devices have failed; and
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that is unmanageable using other techniques.

The device is intended for uncemented use and is single 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)



(Division Sign (1))  
Division of Surgical, Orthopedic,  
and Restorative Devices

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