AUG 15 2005

K050262

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510(k) Summary of Safety and Effectiveness

Submitted By:	United Orthopedic Corporation No. 57, Park Ave. 2, Science Park, Hsinchu, 300, Taiwan Tel: 886-3-5773351 Fax: 886-3-5777156
Date	January 14th, 2005
Contact person	Gene Huang / Regulatory Affairs
Device Name:	U2 Acetabular Component
Common Name:	Acetabular Component
Classification Name and Reference:	21CFR 888.3360 Hip Joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.
Predicate Device:	UNITED U1 Hip Prosthesis (K994078) Howmedica Osteonics Trident® Hemispherical acetabular shells (AD and AD-HA) (K013676) Howmedica Osteonics Trident® Porous Titanium Acetabular Component (K010170)

Device Description:

The U2 Acetabular Component is designated to be used with United U1 hip stem (K994078) and U2 hip stem (K003237) of total hip replacement. It is a modular type of product system. The U2 Acetabular Component has 14 sizes, hemispherical design and without or with clustered bone screw holes for variable screw locking angle. The metallic shell is manufactured from forged Titanium alloy (ASTM F620) and its outer surface has two types of coating: Ti plasma spray and HA/Ti plasma spray. The acetabular liner is machined from extruded UHMWPE bars (ISO 5834/1) and its minimum thickness is 4 18 mm to reduce contact stress. If supplemental bone screw fixation is deemed necessary, Titanium Cancellous Bone Screws (ASTM F136) can be inserted through the screw holes without interfering with the seating of the acetabular liner.

Intended Use:

The U2 Acetabular Component 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 U2 Acetabular Component is designed for uncemented application and is single use only.

Mechanical test data:

The static tensile and shear strengths of HA/Ti plasma spray and the push-out, lever-out and torque-out test data for the liner-cup locking mechanism indicated that U2 Acetabular Component is substantial equivalent to the predicate devices.

Substantial Equivalence Information:

The design concept, material composition, HA coating and locking mechanism of U2 Acetabular Component are similar with currently marketed predicate devices. The U2 Acetabular Component is substantial equivalent to the predicate devices, UNITED U1 Hip system (K994078) and Howmedica Osteonics Trident® Hemispherical acetabular shells (AD and AD-HA) (K013676).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2005

Mr. Gene Huang
Manager Regulatory Affairs
United Orthopedic Corporation
No. 57, Park Avenue 2, Science Park
Hsinchu
China (Taiwan) 300

Re: K050262
Trade/Device Name: U2 Acetabular Component
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: II
Product Code: LWJ, MEH
Dated: July 12, 2005
Received: July 15, 2005

Dear Mr. Huang:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K050262

Device Name: U2 Acetabular Component

Indications for Use:

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

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

The U2 Acetabular Components are designed for uncemented application and single use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K050262