K062978

510(k) Summary of Safety and Effectiveness

JAN 16 2007

Company: United Orthopedic Corporation
Address: No 57, Park Ave. 2, Science Park, Hsinchu, 300, Taiwan
Phone Number: 886-3-5773351
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Date Prepared: September 28, 2006.

Device Name: U2 Hip stem, Ti plasma spray
Common Name: Cementless hip stem
Classification Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (888.3360)
Predicate Device: Reach ® Hip Stem, Ti plasma spray (K000760)
United U2 HA/Ti Plasma Spray (K003237)

Device Description:

The U2 Hip Stem, Ti plasma spray is composed of a metallic femoral stem, which is designed to articulate with commercially available U1 and U2 acetabular components and femoral heads. They are manufactured from titanium alloy (ASTM F620). The stems are designed to provide secure fit and fixation in revision hip arthroplasty for anteroposterior bone loss, calcar area defects, metaphyseal and diaphyseal bone loss situation. The U2 Hip Stem have a 130° neck angle and Morse taper to receive modular femoral heads. The U2 Hip Stem are available in with collar and collarless types. Each type is available in two lengths, 180mm and 230mm, and 7 diameters: 11mm, 12mm, 13mm, 14mm, 15mm, 16.5mm, 18mm. Distally, the stem is cylindrical with a polished bullet shape tip. The 180mm U2 Hip Stem is available as a straight stem, the 230mm femoral stem has an anterior bow for left and right specific applications. The U2 Hip Stem are fully coated with CP Ti (ASTM F1580). The coating is sprayed with CP Ti powder in thickness 500 μm +/-100 μm using 200~350 μm powder to establish a rough surface for press-fit fixation. **This device is a single use implant and intended for cementless use only.**

Intended 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:

1. Non-inflammatory degenerative joint disease such as osteoathritis, 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 are unmanageable using other techniques.

This device is a single use implant and intended for cementless use only.

Basis for Substantial Equivalence:

Features comparable to predicate devices, United U2 HA/Ti Plasma Spray (K003237), Reach® Hip Stem, Ti Plasma Spray (K000760), include same materials, design and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

United Orthopedic Corporation
% Mr. Gene Huang
Regulatory Affairs Coordinator
No. 57, Park Avenue 2, Science Park
Hsinchu, Taiwan 300

JAN 16 2007

Re: K062978
Trade/Device Name: U2 Hip Stem, Ti Plasma Spray
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: LWJ
Dated: December 28, 2006
Received: January 3, 2007

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510 (k) Number (if known): K062978

Device Name: U2 Hip stem, Ti plasma spray

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:

- Non-inflammatory degenerative joint disease such as osteoathritis, 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.

This device is a single use implant and intended for cementless 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)

Barbara Mechlin

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

510(k) Number K062978