

DEC - 4 2000



U1 HIP SYSTEM

Summary

510(k) Summary of Safety and Effectiveness

Company: United Orthopedic Corporation
Address: No 57, Park Ave. 2, Science Park, Hsinchu, 300, Taiwan
Phone Number: 886-3-5773351
Fax Number: 886-3-5777156
Date Prepared: November 16, 1999.

Device Name: U1 Hip System
Common Name: Hip joint prostheses or replacement
Classification Name: Hip joint, Semi-Constrained, Metal/Polymer, Porous Uncemented Prosthesis per 21CFR 888.3358.
Predicate Device: DePuy AML® Hip Prosthesis

Device Description:

The U1 Hip System is designated as a total hip joint replacement. It is a modular type of product system. The followings are the major design features.

Femoral Stem: The component has seven sizes of options, tri-wedge design, straight stem, 134° neck-stem angle, a Morse type taper to receive modular heads, porous coated surface on proximal portion and satin finished on distal. There are w/ and w/o calcar collar designs. This device is produced from cast Co-Cr-Mo alloy (ASTM F75).

Femoral Head: The head diameter is 26mm. There are four adjustments of options, Std, +3, +6, +9, respectively. It is fabricated from wrought Co-Cr-Mo alloy bars (ASTM F1537) by machining.

Acetabular Component: This device has ten sizes of options, hemispherical design, porous coated surface on metallic shell, clustered bone screw holes, spherical screw holes for variable screw locking angle, PMMA cement plug, easy snap-in and take out mechanism, 16 options for angle adjustment, minimum 4.33mm thickness of UHMWPE liner. The metallic shell is produced from cast Co-Cr-Mo alloy (ASTM F75). The plastic liner is machined from extruded UHMWPE bars (ISO 5834/1)

Bone Screw: This device is a 6.5 mm cancellous bone screw. It has six lengths of options (15 mm ~ 40 mm), and has a shallow screw head.

Intended Use:

The U1 hip system 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 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 are unmanageable using other techniques.

Basis for Substantial Equivalence:

Features comparable to predicate devices, DePuy AML® Hip prosthesis, include Co-Cr-Mo alloy substrate, straight type stem, beaded porous coated surface on the proximal portion of stem and acetabular cup, and Morse taper locked with heads.

Test Results:

The U1 stem was analyzed using finite element analysis. The results for the U1 stem (relative motion, load transfer, etc.) are somewhat less sensitive to changes in friction condition than they are for the more extensively coated AML. The analysis establishes the essential equivalence of the design concepts for the U1 and AML femoral components.

The static tensile and shear strength of the beaded porous coating are more than 20MPa. The porous coating has a volume porosity between 30 and 70 percent, an average pore size between 100 and 1000 microns and a porous coating thickness between 500 and 1,500 microns.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC - 4 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Mellen Liu
Regulatory Affairs Coordinator
United Orthopedic Corporation
57, Park Avenue 2, Science Park
Hsinchu 300, Taiwan, R.O.C.

Re: K994078/S1
Trade Name: U1 Hip System
Regulatory Class: II
Product Code: LPH
Dated: September 8, 2000
Received: September 11, 2000

Dear Mr. Liu:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Mark N. Milbrink

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K994078

Device Name: U1 Hip System

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____
(per 21 CFR 801.109)

OR

Over-The Counter Use _____

for Mah N. Melkerson
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994078