MAR 1 2006

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:	May 12, 2005

Device Name:	U2 Total Knee System
Common Name:	Semi-constrained total knee prostheses
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21CFR 888.3560. This falls under the Orthopedics panel/87.
Predicate Device:	United UKNEE® Total Knee System (K021657)

The data that United Orthopedic Corporation included in this submission show the U2 Total Knee System (Cruciate retaining type and posterior stabilized type) is safe and effective. The U2 Total Knee System comprises a femoral component, which articulates with a polyethylene insert component. The underside of the insert component is flat and is snapped into the metal tibial component. The modular (snap-fit) locking mechanism of the insert components has proven to be safe and effective in the clinical area. The design and sizing of the femoral component correspond to the natural femoral anatomy, enhancing stress distribution and contributing to restore original femoral dimensions and normal rotation, extension and flexion. Each size of femur has the same intercondylar distance and radius of curvature; this feature is replicated on the insert component, thus allowing any size of femur to be matched with any size of tibial component. The dome shape all UHMWPE patellar design provides excellent contact and even distribution of stresses, simplifies implantation by eliminating need for rotational orientation. Test data indicate the U2 Total Knee System performs as well or better than the predicate device in all areas tested. Materials used in the manufacture of the U2 Total Knee System meet the property requirements of the ASTM standards associated with each material.

Device Description:

U2 Total Knee system is the fixed bearing type with cruciate retaining and posterior stabilized design. It is a Patellofemorotibia, polymer/metal/polymer, semi-constrained, cemented knee prosthesis, which has a cobalt-chromium-molybdenum (Co-Cr-Mo) alloy femoral component and Ti alloy tibial component composed of a insert, machined from compressed molded UHMWPE flat, mechanical locked with metallic tibial baseplate. The tibial baseplate component is made of Ti-6Al-4V alloy which has groove for cement fixation. The cruciate retaining type of femoral component has w/ and w/o beaded porous coating design, and the posterior stabilized type has only w/o. The porous coating with two layers of beads has an about 55% of porosity, a 440 um of average pore size, and its thickness is 1.0 +0/+0.3 mm. The patella is machined from extruded UHMWPE bar. This device have 3 pegs and cement groove designed for cemented use only.

Intended Use:

This device is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. This device system is designed for cemented use only.

Basis for Substantial Equivalence:

Features comparable to predicate devices, United UKNEE® Total Knee System (K021657), include femoral components, patellar components, tibial trays and tibial inserts. The femoral components are available in cruciate retaining and posterior stabilized designs. Tibial inserts are available in a range of thickness and in cruciate retained and posterior stabilized designs. The patellar components are available in all plastic on-set designs with dome shape configurations.

Test Results:

The U2 Total Knee System was analyzed following draft guidance for cemented, semi-constrained total knee prostheses. The range of motion for the U2 Total Knee System is 135°, satisfying necessary needs of daily life and general activities which exclude placing the patient in condition of severe loading caused higher risk for failure of the knee replacement, such as obesity, heavy labor, active sports participation, high levels of patient activity, likelihood of falls, alcohol or drug addiction and other disabilities, as appropriate.

Constraint testing compares with the UKNEE® Total Knee System and showed the U2 Total Knee System to be slightly more constraint.

Contact area between the femorotibial joint and patellofemoral joint is conducted respectively, and compared with other two products, AMK® and UKNEE®. From the data, we can find U2 Total Knee System could provide similar or greater contact area than others.

Comparing the tibial insert and tibial tray locking testing with UKNEE®, the average anteroposterior motion at 100N load of U2 Total Knee System is less than the predicated device, which means the locking mechanism of U2 Total Knee System is stronger than UKNEE®.

Cyclic test is performed on U2 system to evaluate the fatigue properties of tibial baseplate. Compressive cyclic load between 200N and 2.0KN, 5 million cycles is applied to the test system. There is no fracture on the tibial baseplate.

The static tensile strength of the beaded porous coating was conformed to endure 5,000 psi min. The shear strength of the beaded porous coating was more than 20 MPa. The porous coating has volume porosity between 30 and 70 percent, an average pore size between 100 and 1000 microns and a porous coating thickness between 1,000 and 1,300 microns.

Based on previous test results, the U2 Total Knee System is substantial equivalent to UKNEE® Total Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2006

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

Re: K051640
Trade/Device Name: U2 Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JWH
Dated: February 24, 2006
Received: February 27, 2006

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/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson, M.S.
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): K051640

Device Name: U2 Total Knee System

Indications for Use:

This device is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.

This device system is designed for cemented 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 _____