AUG 1 2 2002

K021657

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
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Date Prepared:	May 14, 2002

Device Name:	UKNEE 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:	Osteonics Omnifit® Total Knee System, Kirschner Performance® Total Knee System and Smith & Nephew, Genesis® Total Knee System

The data that United Orthopedic Corporation included in this submission show the UKNEE Total Knee System (Cruciate retaining type and posterior stabilized type) is safe and effective. The UKNEE Total Knee System comprises a femoral component, which articulates with a fully 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 UKNEE Total Knee System performs as well or better than the predicate device in all areas tested. Materials used in the manufacture of the UKNEE Total Knee System meet the property requirements of the ASTM standards associated with each material.

Device Description:

The design of the UKNEE Total Knee System covers both of the cruciate retaining and posterior stabilized types. 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 tibial component composed of a insert, machined from compressed molded UHMWPE flat, mechanical locked with metallic tibial baseplate. There are two types of tibial baseplate component, one is one piece with grooved but without beaded porous coating and the other is modular, with and/or without beaded porous coating, locked with a keeled or round stem by means of Morse Taper. 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 μm of average pore size, and its thickness is 1.2 +0/+0.3 mm. The patellar components are machined from extruded UHMWPE bar and 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.

Basis for Substantial Equivalence:

Features comparable to predicate devices, Kirschner Performance ® Total Knee System, Osteonics Omnifit® Total Knee System and Smith & Nephew Genesis ® Total Knee System, include femoral components, patellar components, tibial trays, tibial inserts, tibial stems and bone augmentation wedge components. These components are available with or without porous coating. The femoral components are available in cruciate retaining and posterior stabilized designs. The tibial tray components are available in fixed and modular intramedullary stem versions. Tibial inserts are available in a range of thickness and in cruciate retained and posterior stabilized designs. The modular stems are available in round and keeled types with a variety of stem lengths. The stem is assembled via the locking taper. The patellar components are available in all plastic in-set and on-set

designs with dome shape configurations. The bone augmentation wedges are initially cemented to the appropriate tibial component and then cemented to the prepared underlying bone.

Test Results:

The UKNEE Total Knee System was analyzed following draft guidance for cemented, semi-constrained total knee prostheses. The range of motion for the UKNEE Total Knee System is from 0 ° to 115 °, 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 the Omnifit® Total Knee System and showed the UKNEE® Total Knee System to be slightly less constraint.

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

The Morse taper design is applied to the locking mechanism between tibial baseplate and stem. The pull off and torsional resistance strength are 444 kgf and 4.56 kgf-m respectively. When compared with Genesis®, which are 340 kgf and 1.44 kgf-m, it is substantial to or better than the predicated device.

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

Cyclic test is performed on UKNEE 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 lateral stability of UKNEE Total Knee System is compared to the Omnifit® Total Knee System. Test results show the UKNEE knee prosthesis can provide larger stability of patellofemoral joint to prevent lateral dislocation than Omnifit knee prosthesis.

The static tensile strength of the beaded porous coating was conformed to endure 5000 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 500 and 1,500 microns.

Based on previous test results, the UKNEE Total Knee System is substantial equivalent to Osteonics Omnifit® Total Knee System, Kirschner Performance® Total Knee System and Smith & Nephew Genesis® Total Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Philip Leung
Regulatory Affairs
United Orthopedic Corporation
No. 57, Park Avenue
2, Science Park
Hsinchu, Taiwan,
Republic of China

Re: K021657
Trade/Device Name: UKnee Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: May 14, 2002
Received: May 20, 2002

Dear Mr. Leung:

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.

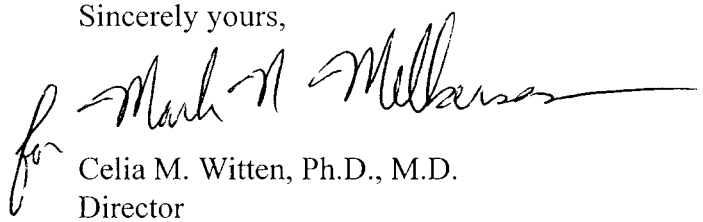
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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): K021657

Device Name: UKnee 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 patello femoral 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use No

(Optional Format 1-2-96)

for Mark N Milhous

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

510(k) Number K021657