K082424

DEC 1 6 2008

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 ext. 331
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Date Prepared:	August 07, 2008

Device Name:	U2 Total Knee System – PSA Type
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.
Predicate Device:	1. "UNITED" U2 Total Knee system (K051640) 2. "ZIMMER" NexGen Complete Knee Solution Legacy CCK Type (K960279)

U2 Total Knee System – Posterior Stabilized Augmentable (PSA) Type is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require constrained stabilization for tibiofemoral joint due to soft tissue imbalance. The U2 Total Knee System – PSA Type comprises a femoral component, which articulates with an ultrahigh molecular weight polyethylene insert component. The undersurface of the insert component is flat and is snapped into the metal baseplate component. The modular (snap-fit) locking mechanism of the insert components has proven to be safe and effective in the clinical area. The U2 Total Knee System – PSA Type collocate with dome shape all UHMWPE patellar (K051640), which provides excellent contact and even distribution of stresses, simplifies implantation by eliminating need for rotational orientation. The U2

Total Knee System – PSA Type also includes femoral augment set, tibial augment, stem component, offset stem adapter, and femoral screw. These assembled components are designed for use to advance the stability of knee joint or the option for surgeon in both difficult primary and revision surgeries. Test data indicate the U2 Total Knee System – PSA Type performs as well or better than the predicate devices in all areas tested. Materials used in the manufacture of the U2 Total Knee System – PSA Type meet the property requirements of the ASTM standards associated with each material.

Device Description:

"UNITED" U2 Total Knee System – Posterior Stabilized Augmentable (PSA) type is an extended design of "UNITED" U2 Total Knee system. It is a Patellofemorotibia, polymer/metal/polymer, semi-constrained, cemented knee prosthesis, which has a cobalt-chromium-molybenum (Co-Cr-Mo) alloy femoral component and a tibial component composed of a polyethylene insert machined from compressed molded UHMWPE and a Ti-6Al-4V metallic tibial baseplate. This system is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock. There are a variety of components including femoral augment set, tibial augment, stem extension and offset stem adapter that provides more choices for surgeon to treat their patients. In addition, this system also provides more constraint of tibiofemoral joint when patients require more constrained stabilization due to inadequate mediolateral, anterioposterior or varus-valgus soft tissue imbalance. The components of U2 Total Knee system-PSA Type are listed as below.

"UNITED" U2 Total Knee System – PSA Type

- Femoral component, PSA type
- Tibial insert, PSA type
- Tibial baseplate
  - Tibial baseplate, PSA type, screw locking

- Tibial baseplate, PSA type

➢ Femoral augment set
  - Femoral augment, Posterior
  - Femoral augment, Distal

➢ Tibial augment
  - Tibial augment, screw locking
  - Tibial augment

➢ Stem component
  - Straight stem, PSA type
  - Curved stem, PSA type
  - Straight stem, PSA type, cemented
  - Curved stem, PSA type, cemented

➢ Offset stem adapter

➢ Femoral screw

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 contraction. This device is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require constrained stabilization for tibiofemoral joint due to soft tissue imbalance.

Basis for Substantial Equivalence:

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The safety and effectiveness of U2 Total Knee system – PSA Type are substantial equivalence to the "UNITED" U2 Total Knee System – PS Type which was previously cleared by FDA (K051640). In addition, U2 Total Knee system – PSA Type is also substantial equivalence to the "ZIMMER" NexGen Complete Knee Solution Legacy CCK Type (Zimmer – LCCK) which was previously cleared by FDA (K960279). Both these two devices were designed to provide more constrained of tibiofemoral joint.

Performance Test – Bench:

The following tests were performed:

1. Tibiofemoral Range of Motion
2. Finite Element Analysis of Tibial Tray
3. Constraints of the Tibiofemoral Joint
4. Contact Area and Contact Pressure in Tibiofemoral Joint
5. Articulating Surface Finish of Femoral Component and Tibial Insert
6. Locking Strength of Tibial Component
7. Fatigue Test for Metal Tibial Baseplate
8. Fatigue Test for Tibial Insert Spine

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

United Orthopedic Corporation
% Mr. Rudy Chen
Regulatory Affairs
No. 57, Park Avenue 2, Science Park,
Hsinchu, 300 Taiwan

DEC 16 2008

Re: K082424
Trade/Device Name: U2 Total Knee System – PSA Type
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: December 12, 2008
Received: December 16, 2008

Dear Mr. Chen:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Indication for Use

510 (k) Number (if known): **k082424**

Device Name: U2 Total Knee System – PSA Type

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K082424