510(k) Summary of Safety and Effectiveness

JAN 15 2014

Submitted by:	United Orthopedic Corporation
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Date of Summary:	June 21, 2013
Contact Person	Fang-Yuan Ho Regulation and Document Management
Proprietary Name:	U2 Tibial Baseplate- CMA type, Tibial Insert and Augment
Common Name:	Semi-constrained total knee prostheses
Device Classification Name and Reference:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21CFR 888.3560. This falls under the Orthopedics panel.
Device Class	Class II
Panel Code	Orthopaedics Device
Device Product Code:	JWH
Predicate Device:	1. "UNITED" U2 Total Knee System (K051640) 2. "UNITED" U2 XPE Total Knee System (K103733) 3. "UNITED" U2 Total Knee System-PSA Type (K082424) 4. "UNITED" Augment and Screw, PSA Type (K122183) 5. "ZIMMER" NexGen Complete Knee Solution L.P.S. Flex Fixed Bearing Knee (K991581)

Device Description:

The subjected device is designed for the replacement of the bearing and/or articulating surfaces of the proximal tibia composed of an articulating bearing surface fixed in a metal tibial baseplate, and is used for patients in primary or revision surgery who require

augmentation and/or stem extensions due to inadequate bone stock. This premarket notification includes the following components: U2 Tibial Baseplate—CMA type, #7 Tibial Insert (CR/PS), #7 XPE Tibial Insert (CR/PS) and #7 Tibial Augment.

U2 Tibial Baseplate—CMA (Cemented Modular Augmentation) is manufactured from titanium alloy forging (ASTM F620) which is forged by titanium alloy bars (ASTM F136) with seven proportional sizes (#1 to #7). Tibial Insert and XPE insert, including PS type and CR type, is an additional size extension to the previously cleared "UNITED" U2 Total Knee System (K051640, K103733). It is manufactured from UHMWPE (ASTM F648/ISO 5834) with five available thicknesses (9, 11, 13, 15, and 18 mm). Tibial Augment is an additional size extension to the previously cleared "UNITED" U2 Total Knee System-PSA Type (K082424, K122183). It is manufactured from Ti-6Al-4V alloy (ASTM F136/ISO 5832-3) with three available thicknesses (5, 10, 15mm).

Indications:

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 may also be indicated in the salvage or previously failed surgical attempts or for knee in which satisfactory stability in flexion cannot be obtained at the time of surgery. This device system is designed for cemented use only.

Basis for Substantial Equivalence:

a. Tibial Baseplate— CMA

The Tibial Baseplate— CMA has the same basic design, intended use, materials and the same manufacturing method as the tibial baseplate of the "United" U2 Total Knee System

and "United" U2 Total Knee System—PSA. Like the "United" U2 Total Knee System—PSA, the Tibial Baseplate— CMA can be used with extension stem and augments. Besides, the Tibial Baseplate— CMA has the same basic design, intended use, material as the tibial plate of "Zimmer" NexGen Complete Knee Solution L.P.S. Flex Fixed Knee.

b. Tibial Insert

Tibial Insert, including PS type and CR type, is an additional size extension of tibial insert of the previously cleared "UNITED" U2 Total Knee System (K051640), while the subjected XPE insert is an additional size extension of the previously cleared "UNITED" U2 XPE Total Knee System (K103733). The materials, design, manufacturing process of the tibial insert and XPE insert are identical to the cleared tibial inserts of "UNITED" U2 Total Knee System and "UNITED" U2 XPE Tibial Inset, respectively.

c. Tibial Augment

Tibial augment—screw locking is an additional size extension to the previously cleared "UNITED" U2 Total Knee System – PSA Type (K082424, K122183). The materials, design, manufacturing process of this device are identical to the cleared tibial inserts of "UNITED" U2 Total Knee System—PAS type.

Performance Data:

Tests as follows were conducted to evaluate the safety and effectiveness of the subjected device, and the test results demonstrated that this device is safe and effective.

a. Locking Strength of Tibial Insert
b. Contact Area and Contact Pressure
c. Wear Simulation
d. Range of Motion
e. Fatigue Test of Tibial Baseplate
f. Fatigue Test of Tibial Insert Spine

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 15, 2014

United Orthopedic Corporation
Fang-Yuan Ho
Regulatory Affairs Manager
No. 57, Park Avenue 2, Science Park
Hsinchu, 300
TAIWAN

Re: K131864
Trade/Device Name: U2 Tibial Baseplate-CMA type, Tibial Insert and Augment
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: December 5, 2013
Received: December 11, 2013

Dear Fang-Yuan Ho:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510 (k) Number (if known): K131864

Device Name: U2 Tibial Baseplate- CMA type, Tibial Insert and Augment

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 contraction. This device may also be indicated in the salvage or previously failed surgical attempts or for knee in which satisfactory stability in flexion cannot be obtained at the time of surgery. This device system is designed for cemented use only.

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)

Elizabeth L Frank -S

Division of Orthopedic Devices