



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

United Orthopedic Corporation
Fang-Yuan Ho
Regulatory Affairs Manager
Number 57, Park Avenue 2, Science Park
Hsinchu 300
Taiwan

September 25, 2015

Re: K150829

Trade/Device Name: U2 Total Knee System-Additional Sizes

Regulation Number: 21 CFR 888.3650

Regulation Name: Knee joint patellofemorobial polymer/metal semi-constrained cemented
prosthesis

Regulatory Class: Class II

Product Code: JWH

Dated: March 20, 2015

Received: March 30, 2015

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 Industry and Consumer Education 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" (21CFR 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure



510(k) Summary of Safety and Effectiveness

Submitter Information

Name	United Orthopedic Corporation
Address	No 57, Park Ave 2, Science Park, Hsinchu 300, Taiwan
Phone Number	+886-3-5773351 ext. 2212
Fax Number	+886-3-577156
Name of Contact Person	Fang-Yuan Ho
	Regulation and Document Management
Date prepared	March 20, 2015

Name of Device

Trade Name	U2 Total Knee System—Additional Sizes
Common Name	Total Knee Prosthesis

Classification Name and Regulation

Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis under 21CFR §888.3560

Device Class

Class II

Classification Panel

Orthopaedics

Product Code

JWH

Predicate Device

1. “UNITED” U2 Total Knee System (K051640)
2. “UNITED” U2 XPE Total Knee System (K103733)
3. “UNITED” U2 Femoral Component, PS, #7 (K120507)
4. “UNITED” Tibial inserts, #7 (K131864)
5. “UNITED” Ultracongruent Insert (K132752)
6. “UNITED” U2 Femoral Component, CR, Cemented (K140073)

Device Description:

This subjected device includes femoral component, tibial insert, XPE tibial insert and



ultracongruent insert. It is a size extension to the cleared "UNITED" U2 Total Knee System (K051640, K120507, K131864, K103733, K132752, and K140073). The indications, materials, design of this subject device are identical to the cleared "UNITED" U2 Total Knee System except for its dimension.

Intended Use:

The U2 Total Knee system 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 is a single use implant and intended for cemented use only.

Comparison to Predicate Device:

U2 Total Knee System, Additional Sizes has the same basic design, intended use, materials and the same manufacturing method as device of the "United" U2 Total Knee System (K051640, K120507, K131864, K103733, K132752 and K140073). The only difference between the cleared and subjected device is dimension.

Performance Data:**● Non-clinical Performance**

This 510(k) submission was prepared in accordance with the Agency's, " *Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA*". 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. Range of Motion
- b. Contact Area and Contact Pressure on Femorotibial Joint
- c. Contact Area and Contact Pressure on Femoropatellar Joint
- d. Constraint of Femoroltibial Joint
- e. Fatigue Compression Test of Femoral Component
- f. Locking Strength of Tibial Insert
- g. Fatigue Performance of Tibial Insert Spine
- h. Materials Properties of U2 XPE Tibial Insert

● **Clinical Performance Data/Information**

None provided as a basis for substantial equivalence.