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

March 16, 2017

United Orthopedic Corporation
Karen Ho
Regulatory Affairs Manager
No 57, Park Ave 2
Science Park
Hsinchu, 300 TW

Re: K161705
Trade/Device Name: U2 Total Knee System E-XPE Products
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, OIY, MBH
Dated: February 9, 2017
Received: February 13, 2017

Dear Ms. 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" (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 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,

Lori A. Wiggins -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161705

Device Name
U2 Total Knee System E-XPE Products

Indications for Use *(Describe)*

For E-XPE Insert (CR, PS and UC type) and Patella:
The 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 is a single use implant and intended for cemented use only.

For E-XPE Insert (PSA type)
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. This device is a single use implant and intended for cemented use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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	Karen Ho Regulation and Document Management
Date prepared	June 15, 2016

Name of Device

Trade Name	**U2 Total Knee System E-XPE Products**
Common Name	Total Knee Prosthesis
Regulation Name and Number	"Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis." under 21CFR §888. 3560 "Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis." under 21CFR §888. 3565
Device Class	Class II
Classification Panel	Orthopaedics
Product Code	JWH, OIY, MBH
Predicate Device	1. U2 Total Knee System- Insert and Patella (K051640, K103733, K131864, K132752 and K150829), United Orthopedic Corporation. 2. U2 Total Knee System-PSA Type (K082424), United Orthopedic Corporation. 3. A200 Knee System (K120038), Renovis Surgical Technologies. 4. PFC Sigma" Knee System (K943462, K961685), Depuy 5. Vanguard DCM Convetional Tibial Bearings (K113550), Biomet

Device Description:

The subjected device includes E-XPE Tibial insert (CR, PS, UC and PSA type) and E-XPE Patella. It is an extension to the previously cleared "UNITED" U2 Total Knee System (K082424, K103733, K131864, K132752 and K150829). The design rationale and indication for use are identical to the previously cleared "UNITED" U2 Total Knee System.

Indications for Use:

For E-XPE Insert (CR, PS and UC type) and Patella:

The 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 is a single use implant and intended for cemented use only.

For E-XPE Insert (PSA type)

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. This device is a single use implant and intended for cemented use only.

Comparison to Predicate Device:

The design rationale and indication for use are identical to the previously cleared "UNITED" U2 Total Knee System (K082424, K103733, K131864, K132752 and K150829). The E-XPE material is substantially equivalent to "Renovis Surgical Technologies" A200 Knee System (K120038). The using instruments are also identical to the predicate devices.

The differences between the subject and the predicate devices are size distribution, device dimension and material. The performance evaluation of the subject device was conducted and would not post issues about safety and effectiveness. Thus, we believe that the subjected device is substantially equivalent to predicate devices.

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. Tibiofemoral Range of Motion (ROM) Analysis
b. Contact Area and Contact Pressure on Femorotibial Joint
c. Constraint of Femoroltibial Joint
d. Locking Strength of Tibial Insert
e. Wear Simulation Test
f. Fatigue Test of Tibial Insert Spine

g. Mechanical Properties of E-XPE Material

Bacterial endotoxin testing was conducted and met the endotoxin limit as specified in USP <161>.

- **Clinical Performance Data/Information**

  None provided as a basis for substantial equivalence.