April 21, 2021

United Orthopedic Corporation
Lois Ho
Regulatory Affairs Manager
No 57, Park Ave 2, Science Park
Hsinchu, 30075
TAIWAN

Re: K210961
Trade/Device Name: U2 Total Knee System, XPE Tibial Insert, PS PLUS
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: March 31, 2021
Received: March 31, 2021

Dear Lois 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ting Song, Ph.D., R.A.C.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210961

Device Name

U2 Total Knee System, XPE Tibial Insert, PS PLUS

Indications for Use *(Describe)*

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 cannot be satisfactorily balanced and stabilized at the time of surgery.

For cemented femoral components, patellar components, tibial baseplate components and tibial inserts components: This device is a single use implant and intended for cemented use only.

For porous coated femoral component: This device is a single use implant and intended for cementless 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.

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Special 510(k)
U2 Total Knee System, XPE Tibial Insert, PS Plus

510(K) SUMMARY
Special 510(k)

[as required by 21 CFR 807.92(c)]

Submitter information

Company Name:	United Orthopedic Corporation
Address	No 57, Park Ave 2, Science Park, Hsinchu City 30075, Taiwan
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Contact Person	Lois Ho, Regulatory Affairs Manager
Email address	lois.ho@unitedorthopedic.com
Date of submission	March 30, 2021

Trade Name, Common Name, Classification

Device Common Name:	Tibial Insert
Trade name:	U2 Total Knee System, XPE Tibial Insert, PS Plus
Submitter Establishment Number:	9681642
Classification Regulation Number:	21CFR 888.3560
Classification Panel:	Orthopedic
Product Code:	JWH
Device Class:	Class II
Classification name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Predicate devices and reference devices

Primary Predicate	**510(k) Number**	**Manufacturer**
U2 Total Knee System, Tibial Insert, PS	K150829	United Orthopedic Corporation
Reference Predicate		
U2 Total Knee System, Tibial Insert, PS	K103733, K131864, K161705	United Orthopedic Corporation

Device description	The U2 Total Knee System include femoral components, patellar components, tibial baseplate components and tibial inserts components which are designed to be used together to achieve total replacement of the knee joint. This system includes Cruciate Retained (CR) type,

	Posterior Stabilized (PS) type and Ultracongruent (UC) type. The subject device, U2 Total Knee System, XPE Tibial Insert, Posterior Stabilized PLUS (PS PLUS), belongs to U2 Total Knee System PS type. U2 Total Knee System, XPE Tibial Insert, PS PLUS (Subject device) is a constrained design insert mechanically locked with metallic tibial baseplate. It is manufactured from Gamma irradiated UHMWPE which conform to ASTM F2565-13, while the UHMWPE raw material is in accordance with ASTM F648-14 and ISO 5834-1:2005. The Subject device is used with the Posterior Stabilized (PS) type Femoral Component. In comparison to the marketed predicate devices, the Subject device has slightly modified width and height of the post, the height of the anterior lip. The Subject device provides constraint in varus/valgus and internal/external rotation to enhance joint stability and resist paradoxical anterior femoral slide. Except for the differences of the post and anterior lip, the size distribution the Subject device is identical to the previously cleared Tibial Inserts of U2 Total Knee System predicates. The Subject device is available in eight proportional sizes (#0~ #7) and ten thicknesses (thicknesses of poly insert + tibial baseplate: 9mm, 10mm, 11mm, 12mm, 13mm, 14mm, 15mm, 16mm, 17mm and 18mm). The minimum thickness of poly insert of Subject device is 6 mm on the bearing surface, identical to the primary predicate. Surgical procedures with the use of the Subject device shall be performed with the support of orthopedic instrumentation, to facilitate their proper insertion and removal from the patient. The surgical instruments have been previously cleared as part of the predicate devices.
Indications for 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 cannot be satisfactorily balanced and stabilized at the time of surgery.

Special 510(k)
U2 Total Knee System, XPE Tibial Insert, PS Plus

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Technological Characteristics	The Subject device fundamental scientific principles and technological characteristic, including: the intended use, material and general design, are the same as, or similar to, the primary predicate and the chosen additional predicate device. Summary of the technological characteristics: ✓ *Intended use*: identical ✓ *Indications for Use, Anatomical sites, operating principles and conditions of use* are identical ✓ No new risks associated to the Subject device compared to those of the predicate devices. ✓ Verification activities on Subject devices demonstrated equivalent safety and effectiveness as compared to the predicate devices. ✓ *Material:* are identical to the primary predicate. ✓ *Geometry and size*: Sizes of the Subject device are bracketed in size by the predicates. ✓ *Sterilization*: identical method as predicate. The *technological characteristics* of the Subject device are substantially equivalent to the predicate device(s).
Performance Analysis	Based on the modification items of the design rational of the Subject device, the following tests were conducted to evaluate the safety and effectiveness of the subjected device, and the test results indicated that this device is safe and effective. • Constraint evaluation • Contact area and contact pressure analysis on femorotibial joint • Tibiofemoral range of motion (ROM) analysis
Conclusion	Based upon equivalences in: intended use, patient population, site of application, conditions of use, operating principles, and the non-clinical performance data, the changes introduced in the Subject device have been shown to be safe and effective and to perform equivalently as compared to the legally marketed predicate devices. Therefore, the changes to primary predicate for Subject devices are substantially equivalent to the legally marketed predicate devices.