February 28, 2023

United Orthopedic Corporation
Cheryl Wagoner
Official Correspondent
5215 Crosswinds Drive
Wilmington, North Carolina 28409

Re: K221705
Trade/Device Name: U2 Total Knee System-PF+
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: January 30, 2023
Received: January 31, 2023

Dear Cheryl Wagoner:

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 -S

Ting Song, Ph.D.
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)*

K221705

Device Name
U2 Total Knee System- PF+

Indications for Use *(Describe)*

U2 Total Knee System - PF+ 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 joint surface erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. 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. Femoral Component, PF+, Tibial Baseplate, PF+ and Tibial Extension Stem are indicated for both cemented and cementless use.

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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510(K) SUMMARY
Traditional 510(k)

[as required by 21 CFR 807.92(c)]

Submitter information

Company Name:	United Orthopedic Corporation
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Telephone	+886-3-5773351 ext. 2220
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Contact Person	Lois Ho, Regulatory Affairs Manager
Email address	lois.ho@unitedorthopedic.com
Date of submission	June 10, 2022

Trade Name, Common Name, Classification

Device Common Name:	Femoral component, Tibial baseplate, Tibial stem
Trade name:	U2 Total Knee System- PF+
Submitter Establishment Number:	9681642
Classification Regulation Number:	21CFR 888.3565
Classification Panel:	Orthopedic
Product Code:	MBH, JWH
Device Class:	Class II
Classification name:	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis

Predicate devices

Primary Predicate		
Product name	Manufacturer	510(k) Number
U2 Femoral Component, CR, Porous Coated	United Orthopedic Corporation	K140075, K150832
Predicate or Reference Device		
U2 Total Knee System	United Orthopedic Corporation	K051640, K120507, K150829
Truliant® Porous Femoral Components	Exactech	K181794
Triathlon® Tritanium Tibial Baseplates	Stryker	K123486
Klassic® Tibial Baseplate, Porous	Total Joint Orthopedics	K162256
Klassic™ Knee Tibial Stem Extension	Total Joint Orthopedics	K140942
USTAR II Knee System	United Orthopedic Corporation	K190100
U2 Hip stem, Ti porous coated, matrix	United Orthopedic Corporation	K151316

Device description	There are three components included in U2 Total Knee System- PF+ for this 510k, (1)Femoral Component, PF+, (2)Tibial Baseplate, PF+, and (3)Tibial Extension Stem. Both Femoral Component, PF+ and Tibial Baseplate, PF+ can collocate with U2 Total Knee System tibial insert and patellar component (K021657, K051640, K082469, K103733, K131864, K132752, K150829, K152430, K161705, and K210961). This system includes Cruciate Retained (CR) type and Posterior Stabilized (PS) type. • Femoral Component, PF+ There are two types of Femoral Component, PF+ : Cruciate Retaining type and Posterior Stabilized type. Femoral Component, PF+ is manufactured from cast Co-Cr-Mo alloy conforming to ASTM F75. The inner surface is coated with Co-Cr-Mo beads and Co-Cr-Mo powder (ASTM F75) to provide a porous surface to achieve biological fixation. • Tibial Baseplate, PF+ Tibial Baseplate, PF+ is manufactured from titanium alloy (ASTM F620) which is forged by titanium alloy bars (ASTM F136). The backside of the subject device is coated with Titanium powder (ASTM F1580). • Tibial Extension Stem Tibial Extension Stem is collocated with tibial baseplate. The subject device is made of titanium alloy conforming to ASTM F136.
Indications for use	U2 Total Knee System - PF+ 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 joint surface erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. 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. Femoral Component, PF+, Tibial Baseplate, PF+ and Tibial Extension Stem are indicated for both cemented and cementless use.
Technological Characteristics	The Subject device fundamental scientific principles and technological characteristics, including: the intended use, material and general design, are the same as, or similar to, the primary predicate and the chosen additional predicate/reference devices. 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 predicates. 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 rationale 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. • Femoral component fatigue test • Tibial baseplate fatigue test • Articulating surface finish of femoral component • Finish of non-articulating surface of tibial baseplate • Microstructure of the modified surface • Mechanical properties of the modified surface • Bacteria endotoxin testing was conducted and met the endotoxin limit as specified in USP<161>
Conclusion	Based upon equivalences in: intended use, patient population, site of application, conditions of use, operating principles, and the non-clinical performance data, the Subject device has been shown to be safe and effective and to perform equivalently as compared to the legally marketed predicate devices. Therefore, the Subject devices are substantially equivalent to the legally marketed predicate devices.