October 6, 2022

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

Re: K222700
Trade/Device Name: Tibial baseplate, Tibial insert
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: September 2, 2022
Received: September 7, 2022

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. RAC
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)*
K222700

Device Name
Tibial baseplate, Tibial insert

Indications for Use *(Describe)*

For Tibial baseplate, CMA, #0

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 joint surface 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.

For Tibial insert, #0

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.

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
Special 510(k)

[as required by 21 CFR 807.92(c)]

Submitter information

Company Name:	United Orthopedic Corporation
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Contact Person	Lois Ho, Regulatory Affairs Manager
Email address	lois.ho@unitedorthopedic.com
Date of submission	September 02 2022

Trade Name, Common Name, Classification

Device Common Name:	Tibial baseplate, Tibial insert
Trade name:	U2 Total Knee System, #0
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 per 21CFR 888.3560. This falls under the Orthopedics panel.

Predicate devices

Predicate	510(k) Number	Manufacturer
1. U2 Tibial baseplate, CMA	1. K131864	United
2. Tibial insert, CR and PS type	2. K051640, K150829, K131864	Orthopedic
3. XPE Tibial insert, CR and PS type	3. K103733, K150829, K131864	Corporation

4. XPE Tibial insert, UC type 5. E-XPE Tibial insert, CR and UC and PS type	4. K132752, K150829 5. K161705	

Device description	The U2 Total Knee System consists of Femoral components, patella 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, Ultracongruent (UC) type, and Posterior Stabilized (PS) type. The U2 Total Knee System, Tibial baseplate, CMA, #0 (Subject device) is a size extension of the cleared "UNITED" U2 Total Knee System, Tibial baseplate, CMA, #1 to #7 (K131864). The materials, indications, sterilization of this subject are identical to the cleared "UNITED" U2 Total Knee System, Tibial baseplate, CMA, #1 to #7 (K131864). The U2 Total Knee System, Tibial insert, #0 (Subject device) is a size extension of the cleared "UNITED" U2 Total Knee System, Tibial insert, #1 to #7 (K051640, K103733, K131864, K132752, K150829 and K161705). The materials, indications, sterilization of this subject are identical to the cleared "UNITED" U2 Total Knee System, Tibial insert, #1 to #7 (K051640, K103733, K131864, K132752, K150829 and K161705). The Subject Tibial insert, CR, #0 and Tibial insert, PS, #0 have a more concave sagittal plane design while comparing to the marketed predicate devices 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. All the surgical instruments have been cleared as part of the predicate devices.

U2 Total Knee System #0 *Special 510 (k)*

Indications for use	**For Tibial baseplate, CMA, #0** 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 joint surface 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. **For Tibial insert, #0** 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.
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:* identical. ✓ *Geometry and size*: The size of the subject subject, which owns the smallest diameter, are the extension size of the primary predicates. ✓ *Sterilization*: identical method as predicate. The *technological characteristics* of the Subject device are substantially equivalent to the predicate devices.
Performance Analysis	Based on the modification items of the design rational of the Subject device, the following non-clinical 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. • Range of Motion • Locking Strength of Tibial baseplate and Insert • Contact Area and Contact Pressure • Wear Simulation Test • Fatigue Test of Tibial baseplate • Spine Fatigue Test of Tibial insert The clinical tests was not deemed necessary for the subject device.
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.