July 31, 2025

United Orthopedic Corporation
% Natalie J Kennel
Consultant
NJK & Associates, Inc.
13721 Via Tres Vista
San Diego, California 92129

Re: K243656
Trade/Device Name: U2 Total Knee System - PF+ Patella; USTAR II System- PF+ Patella
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, KRO
Dated: July 2, 2025
Received: July 2, 2025

Dear Natalie J Kennel:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lixin Liu -S

Lixin Liu, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243656

Device Name
U2 Total Knee System – PF+ Patella

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+, Tibial Extension Stem, Patella, Onset, E-XPE, PF+, and Patella, Asymmetric Onset, E-XPE, PF+ 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243656

Device Name
USTAR II System- PF+ Patella

Indications for Use *(Describe)*
USTAR II Total Knee System
1. Metastatic tumor (i.e. osteosarcoma, chondrosarcoma, giant cell tumor or osteoma) where massive resection and transplantation are needed.
2. Severe knee joint damage resulting from trauma where massive resection and transplantation are needed.
3. Non-inflammatory degenerative joint disease such as avascular necrosis, osteoarthritis, or traumatic arthritis.
4. Revision of previously failed total joint arthroplasty, osteotomy, or arthrodesis.
5. Joint instability resulting from excessive bone resection.

For Femoral component, Hinged/ Tibial baseplate, Hinged/ Cemented tibial stem/ Cemented Straight stem, RHS, non coated/ Cemented Curved stem, RHS, non coated/ Cemented Straight stem, RHS/ Cemented Curved stem, RHS/ Tibial Augment: These devices are single use implant and intended for cemented use only.

For Distal Femoral Component, RHS/ Proximal Tibial Component, RHS/ Tibial stem/ Segment Part, RHS/ Segment Part, RHS, Bridge: These devices are 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)

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510(K) SUMMARY

Traditional 510(k)

[as required by 21 CFR 807.92(c)]

Contact Details

Company Name	United Orthopedic Corporation
Company Address	No 57, Park Ave 2, Science Park, Hsinchu City 30075, Taiwan
Company Contact Telephone	+88635773351
Company Contact	Mrs. Lois Ho
Company Contact Email	lois.ho@unitedorthopedic.com
Application Correspondent	Natalie J. Kennel
Application Correspondent Telephone	(858)705-0350
Application Correspondent Email	Nkennel@njkconsulting.com
Date of Preparation	July 30th , 2025

Device Name

Device Trade Name	U2 Total Knee System – PF+ Patella; USTAR II System – PF+ Patella
Common Name	Total Knee Replacement
Classification Name	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulation Number	888.3565, 888.3560, 888.3510
Product Codes	MBH, JWH, KRO

Predicate Device Information

510(k) Number	Predicate Trade Name	Product Code
Primary Predicate		
K212941	Porous Patella e+™	MBH, JWH
Secondary Predicate Devices		
K132624	Triathlon® Tritanium® Metal-Backed Patella	MBH, JWH
K221705	U2 Total Knee System-PF+	MBH, JWH

510(k) Number	Predicate Trade Name	Product Code
K190100	USTAR II System – USTAR II Knee System	KRO, KWL, LPH, LWJ

Device Description Summary	The subject PF+ Patella is a line extension of the U2 Total Knee System, and is compatible to the USTAR II System. The subject device, **U2 Total Knee System–PF+ Patella; USTAR II System - PF+ Patella,** is a Metal-Backed Patella, indicated for both cemented or cementless application. There are two variations available: (1) Patella, Onset, E-XPE, PF+, and (2) Patella, Asymmetric Onset, E-XPE, PF+. Patella, Onset, E-XPE, PF+ is a symmetric, dome-type metal-backed patella, and Patella, Asymmetric Onset, E-XPE, PF+ is an asymmetric, anatomic-type patella. Each type is available in five sizes. The body of **PF+ patella** is manufactured from Vitamin E blended highly cross-linked UHMWPE (ASTM F2695, ASTM F648/ISO5834-1), while the part of the metal back and the three pegs are produced by additive manufacturing according to the FDA guidance "Technical Considerations for Additive Manufactured Medical Devices - Guidance for Industry and Food and Drug Administration Staff", "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement", and "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Post market Surveillance Requirements." The metal back is made of Ti-6Al-4V alloy (ASTM 2924) and has a porous Ti structure on the bone side, peg side, and poly side. All types of **PF+ Patella** are compatibility with "United" U2 Total Knee System-Femoral components (K051640, K120507, K140073, K140075, K150829, and K150832), Femoral component, PSA (K082424), Femoral components, PF+ (K221705), and USTAR II System-Femoral components (K190100).
Intended Use/ Indications for Use	U2 Total Knee System – PF+ Patella 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+, Tibial Extension Stem, Patella, Onset, E-XPE, PF+, and Patella, Asymmetric Onset, E-XPE, PF+ are indicated for both cemented and cementless use. <u>USTAR II System – PF+ Patella</u> USTAR II Total Knee System 1. Metastatic tumor (i.e. osteosarcoma, chondrosarcoma, giant cell tumor or osteoma) where massive resection and transplantation are needed. 2. Severe knee joint damage resulting from trauma where massive resection and transplantation are needed. 3. Non-inflammatory degenerative joint disease such as avascular necrosis, osteoarthritis, or traumatic arthritis. 4. Revision of previously failed total joint arthroplasty, osteotomy, or arthrodesis. 5. Joint instability resulting from excessive bone resection. For Femoral component, Hinged/ Tibial baseplate, Hinged/ Cemented tibial stem/ Cemented Straight stem, RHS, non coated/ Cemented Curved stem, RHS, non coated/ Cemented Straight stem, RHS/ Cemented Curved stem, RHS/ Tibial Augment: These devices are single use implant and intended for cemented use only. For Distal Femoral Component, RHS/ Proximal Tibial Component, RHS/ Tibial stem/ Segment Part, RHS/ Segment Part, RHS, Bridge: These devices are single use implant and intended for cementless use only.
Indications for Use Comparison	The indication for use of the subject device is substantially equivalent to the primary predicate. Although the content of the indication for use is not completely identical, both the subject device and the primary predicate are indicated in knee arthroplasty to reduce or relieve pain and /or improve knee function. In addition, both are intended for cemented or uncemented applications. Based on the above, the indication for use of the subject device is considered substantially equivalent to the primary predicate.

Technological Comparison	The technological characteristics of the subject device are substantially equivalent to those of the primary predicate (K212941), as shown in the comparison given below. - Their intended use is the same. - The items, including materials, fixation method, x-ray visible, provided sterile, prescription device, single-use device, are identical. - The symmetric option of the subject PF+ Patella has different sterilization method and thickness and size ranges compared to the primary predicate device. - The asymmetric option of the subject PF+ Patella has different metal base and UHMWPE materials, and size ranges compared to the secondary predicate, K132624.
Non-Clinical and/or Clinical Tests Summary & Conclusions	Based on the technological characteristics of the subject device, the following evaluation and tests were conducted to validate the safety and effectiveness of the subject device. - Pull-out test - Characterization of Ti prorous coating - Durability test - Usability evaluation - Endotoxin testing No clinical data is necessary. Based upon substantial equivalences in: intended use, patient population, site of application, conditions of use, and the non-clinical performance data, the Subject device has been shown to be as safe and effective and to perform substantially equivalently as compared to the legally marketed predicate devices. Therefore, the Subject device is substantially equivalent to the legally marketed predicate devices.