September 25, 2025

United Orthopedic Corporation
Ms. Lois Ho
Regulatory Affairs Manager
No 16. Luke 1st Rd., Luzhu Dist.
Kaohsiung, 85121
Taiwan

Re: K252725
Trade/Device Name: Stem Extension Line (U2 Total Knee System-PSA Type)
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: August 28, 2025
Received: August 28, 2025

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 (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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2025.09.25 15:13:48 -04'00'

For 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.*

Submission Number *(if known)*

K252725

Device Name

Stem Extension Line (U2 Total Knee System—PSA Type)

Indications for Use *(Describe)*

This device is indicated in knee arthroplasty 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 is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require increased stabilization for tibiofemoral joint due to soft tissue imbalance. The femoral and tibial augments are to be attached to their respective components with a fixation screw or screws.
Note: In the US, this device is 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.**

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.***

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# 510(k) SUMMARY
# Special 510(k)

[as required by 21 CFR 807.92(c)]

## Contact Details

| | |
|---|---|
| Applicant Name | United Orthopedic Corporation |
| Applicant Address | No. 16, Luke 1st Rd., Luzhu Dist., Kaohsiung City 82151, Taiwan |
| Applicant Contact Telephone | +886-3-5773351 |
| Applicant Contact | Lois Ho |
| Applicant Contact Email | lois.ho@unitedorthopedic.com |

## Device Name

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|---|---|
| Device Trade Name | Stem Extension Line (U2 Total Knee System—PSA Type) |
| Common Name | Semi-constrained total knee prosthesis |
| Classification Name | Knee joint patellofemorotibial polymer/ metal/ polymer semi-constrained cemented prosthesis |
| Regulation Number | 888.3560 |
| Product Codes | JWH |

## Legally Marketed Predicate Devices

| Predicate | Predicate Trade Name | Product Code |
|---|---|---|
| K082424 | U2 Total Knee System—PSA Type | JWH |

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| **Device Description Summary** | "UNITED" U2 Total Knee System – Posterior Stabilized Augmentable (PSA) type is a patellofemorotibial polymer/ metal/ polymer, semi-constrained, cemented knee prosthesis, which has a metallic femoral component and a tibial component composed of a polyethylene insert and a metallic tibial baseplate. Tibial inserts are available in two design configurations: for the PSA type insert, it is intended for use in patients who require constrained stabilization of the tibiofemoral joint due to soft tissue imbalance. While the PSA low constrained type (PSA, LC) insert provides less constrained stabilization than the PSA type insert.<br>This system is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock. There are a variety of components including femoral augment set, tibial augment, stem extension and offset stem adapter that provide more choices for surgeon to treat their patients. In addition, this system provides more stability for patients with inadequate |

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| | medial-lateral, anterior-posterior or varus-valgus soft tissue imbalance. For total knee replacement, "UNITED" patella components are intended to be used with the U2 Total Knee System—PSA Type.<br><br>For the subject device, it's a line extension of the 510(K) cleared device U2 Total Knee System—PSA Type (K082424), which introduces the variation, Straight Stem, Cross Slot, PSA, with stem lengths from 75mm to 200mm, diameters from Ø10 to Ø24mm.<br><br>The compatibility of the Straight Stem, Cross Slot, PSA is the same as that of the 510(k) cleared U2 Total Knee System—PSA Type (K082424).<br><br>The Straight Stem, Cross Slot, PSA is an extension of the geometric characteristics of the 510(k) cleared device, U2 Total Knee System—PSA Type (K082424). Its materials, size, locking mechanism, and manufacturing process are identical to that of the 510(k) cleared Straight Stem, PSA. |
| **Intended Use/ Indications for Use** | This device is indicated in knee arthroplasty 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 is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require increased stabilization for tibiofemoral joint due to soft tissue imbalance. The femoral and tibial augments are to be attached to their respective components with a fixation screw or screws.<br><br>Note: In the US, this device is for cemented use only. |
| **Indications for Use Comparison** | The subject device has the same intended use and similar indications for use as the predicate devices. |
| **Technological Comparison** | The technological characteristics of the subject device are substantially equivalent to that of the predicate device U2 Total Knee System (K082424) as the comparison given below.<br>- Their intended use is the same.<br>- The design, material, principle of operation, regulation number, product code, risk class, intended users, fixation method, surface coating, locking mechanism |

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| | of stem locking, and sterilization method of the subject device is the same as that of the predicate device.<br>The design control activities were conducted for the difference in the specification (Cross slot stem and solid stem). They validated equivalent safety and effectiveness compared to the predicate devices based on the same analysis method the previous submission applied.<br>It established that no new risks arise compared to those of the predicate devices. |
| **Non-Clinical and/or Clinical Tests Summary & Conclusions** | The subject device and the predicate device are both compatible with the same tibial baseplates in clinical use. They are fully embedded within the medullary canal and are not the weight-bearing component (The tibial baseplate is the weight bearing component). Thus, we have evaluated the surgical instruments and techniques to determine if there are any changes.<br>The result of the evaluation shows that both the surgical instruments and surgical technique are identical between the subject device and the predicate device. Thus, the Stem Extension Line (U2 Total Knee System—PSA Type) is considered substantially equivalent to the predicate devices (K082424). |