August 22, 2025

United Orthopedic Corporation
Lois Ho
Regulatory Affairs Manager
No 16. Luke 1 st Rd., Luzhu Dist.
Kaohsiung City, 82151
Taiwan

Re: K252303
Trade/Device Name: Stem Extension Line (USTAR II System)
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO, KWL, LPH, LWJ, LZO, OQI
Dated: July 22, 2025
Received: July 24, 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,

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.

Submission Number *(if known)*

K252303

Device Name

Stem Extension Line (USTAR II System)

Indications for Use *(Describe)*

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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	Ms. Lois Ho
Applicant Contact Email	lois.ho@unitedorthopedic.com

Device Name

Device Trade Name	Stem Extension Line (USTAR II System)
Common Name	Total Knee Prosthesis / Total Hip Prosthesis
Classification Name	Knee joint femorotibial metal/polymer constrained cemented prosthesis. Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis. Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Regulation Number	888.3510, 888.3358, 888.3360, 888.3353
Product Codes	KRO, KWL, LPH, LWJ, LZO, OQI

Legally Marketed Predicate Devices

Predicate	Predicate Trade Name	Product Code
K190100	USTAR II System	KRO, LPH, LWJ, KWL

Device Description Summary	"United" USTAR II System is used for patients who present large quantity of bone loss and deformity associated with previous failed arthroplasty, ligament deficiencies, tumor resection, or trauma and may require a further operation or reconstruction. The USTAR II System includes implanted arthroplasty components of both the USTAR II Knee System and USTAR II Hip System. For the subject device, it's an extension line of 510(K) cleared device USTAR II System (K190100), which introduces two new variations: (1) Cemented curved stem, RHS, non-coated: Ø17×200 mm (2) Tibial stem: stem length from 30mm to 150 mm by stem diameter from Ø9 to Ø24

	The compatibility of cemented curved stem, RHS, non-coated and tibial stem is same as that of the 510(k) cleared USTAR II system (K190100). Cemented Curved Stem, RHS, non-coated is an extension in terms of sizes to 510 (k) cleared device USTAR II system (K190100). Its design, materials, geometrical characteristic, locking mechanism, and manufacturing process are identical to that of the 510(k) cleared Cemented Curved Stem, RHS, non-coated. Tibial stem's design, materials, geometrical characteristic, locking mechanism, and manufacturing process are identical to that of the 510(k) cleared Tibial Stem while the only difference lies in its specification
Intended Use/ Indications for Use	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 subject device's intended use is the same as the predicate device with similar indications for use.
Technological Comparison	The technological characteristics of the subject device are substantially equivalent to that of the predicate device USTAR II System (K190100) as the comparison given below. - Their intended use is the same. - The design, material, principle of operation, regulation number, risk class, intended users, fixation method, surface coating, geometry design, locking mechanism of stem locking, and sterilization method of the subject device is the same as that of the predicate device. - The design control activities were conducted for the difference in the specification (stem diameter and stem length). They validated equivalent safety and effectiveness compared to the predicate devices based on the same analysis method the previous submission applied. It established that no new risks arise compared to those of the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions	Mechanical Analyses - Stem fatigue analysis per ISO 7206-4 - Mechanical strength analysis of tibial baseplate collocated with tibial stem per ASTM F1800 and ISO 21536:2023 No clinical tests were performed to support the safety and effectiveness of the subject device. The mechanical analyses were used as a basis for the determination of substantial equivalence. The results of each show that compared to the predicate device, the subject device has met the required acceptance criteria, and there are no additional risks arising. Thus, the Stem Extension Line (USTAR II System) is considered substantially equivalent to the predicate device (K190100).