January 6, 2025

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

Re: K243466
Trade/Device Name: Conformity Stem Extension Line, #0
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH
Dated: October 28, 2024
Received: November 8, 2024

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,

RYAN TROMBETTA -S

For: Limin Sun, 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)*

K243466

Device Name

Conformity Stem Extension Line, #0

Indications for Use *(Describe)*

The device is indicated for use in hip arthroplasty in skeletally mature patients with the following conditions:
1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement or total hip replacement.
5. Certain cases of ankylosis.

Conformity stem is 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.

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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Traditional 510(k)
Conformity Stem Extension line, #0

510(K) SUMMARY

Traditional 510(k)

[as required by 21 CFR 807.92(c)]

Contact Details

Applicant Name	United Orthopedic Corporation
Applicant Address	No 57, Park Ave 2, Science Park, Hsinchu City 30075, Taiwan
Applicant Contact Telephone	+88635773351
Applicant Contact	Mrs. Lois Ho
Applicant Contact Email	lois.ho@unitedorthopedic.com

Device Name

Device Trade Name	Conformity Stem Extension Line, #0
Common Name	Hip Stem
Classification Name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulation Number	888.3353
Product Codes	LZO, MEH

Predicate Device Information

510(k) Number	Predicate Trade Name	Product Code
K183312 (Primary predicate)	Conformity stem, cementless	LZO, MEH
K242249	Conformity stem extension line	LZO, MEH

Device Description Summary	The subject device is an extension line of 510(K) cleared device Conformity stem, cementless (K183312, K242249), which introduces four new variations: (1) Conformity stem, #0; (2) Conformity stem, collared, #0; (3) Conformity stem, coxa vara, 125° STD, collared, #0; and (4) Conformity stem, short neck, collared #0. The indications, design rationales, materials, manufacturing process, and sterilization method of the subject devices are identical to the 510(k) cleared Conformity Stem, cementless (K183312, K242249). Conformity Stem can collocate with "United" metallic femoral heads (K994078, K022520, K111546, K122504, K152439, K162957, K221675) or ceramic femoral heads (K103497, K112463, K122185). - Conformity stem, #0 Conformity stem, #0 is an extension in terms of sizes to 510

Traditional 510(k)
Conformity Stem Extension line, #0

	(k) cleared device Conformity stem, #1-11 (K183312). The material, coating thickness, neck angle (135°), and neck length (35.5mm) design are identical to 510 (k) cleared device Conformity Stem, #1, #11 (K183312)The only differences in the items are the offset specifications and stem length. - Conformity stem, collared, #0 Conformity stem, collared, #0 is an extension in terms of sizes to 510 (k) cleared device Conformity stem, collared, #1-11 (K183312). The material, coating thickness, neck angle (135°), and neck length (35.5mm) design are identical to 510 (k) cleared device Conformity stem, collared, #1, #11 (K183312).The only differences in the items are the offset specifications and stem length. - Conformity Stem, coxa vara, 125° STD, collared, #0 Conformity Stem, coxa vara, 125° STD, collared, #0 is an extension in terms of sizes to 510 (k) cleared device Conformity stem, coxa vara 125° STD, collared, #1-7 (K242249). The material, coating thickness, neck angle (125°), and neck length (32.5mm) design are identical to 510 (k) cleared device Conformity stem, 125° STD, collared, #1, #7 (K242249). The only differences in the items are the offset specifications and stem length. - Conformity Stem, short neck, collared #0 Conformity Stem, short neck, collared #0 is an extension in terms of sizes to 510 (k) cleared device Conformity Stem, short neck, collared, #1-7 (K183312 and K242249). The material, coating thickness, neck angle (135°), and neck length (28.5mm) design are identical to 510 (k) cleared device Conformity Stem, short neck, collared, #1, #7 (K183312 and K242249). The only differences in the items are the offset specifications and stem length.
Intended Use/ Indications for Use	The device is indicated for use in hip arthroplasty in skeletally mature patients with the following conditions: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia. 2. Avascular necrosis of the femoral head. 3. Acute traumatic fracture of the femoral head or neck. 4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement or total hip replacement. 5. Certain cases of ankylosis. Conformity stem is for cementless use only.

Traditional 510(k)
Conformity Stem Extension line, #0

Indications for Use Comparison	The indication for use of the subject device is identical to the predicate devices.
Technological Comparison	The technological characteristics of the subject device are substantially equivalent to those of the predicate device Conformity stem, cementless (K183312) and Conformity stem extension line (K242249) as per the comparison given below: - Their intended use is the same. - The material, principle of operation, regulation number, product code, risk class, intended users, fixation method, surface coating, locking mechanism, and sterilization method of the subject device are the same as those of the predicate device. - Verification activities were conducted to assess the differences in the offset specifications and the stem length sizes between the subject and predicate, using the same analysis methods as the predicate submission.
Non-Clinical and/or Clinical Tests Summary & Conclusions	Based on the design rationale of the Subject device, the following tests were conducted to evaluate the safety and effectiveness of the subject device. • Range of Motion (ISO 21535) • Neck Fatigue Assessment (ISO 7206-6) • Stem Fatigue Test (ISO 7206-4) • Characterization of HA Plasma Spray Coating (FDA guidance "510(k) information needed for Hydroxyapatite Coated Orthopedic Implants") • Usability Evaluation (BS EN 62366-1, FDA guidance "Content of Human Factors Information in Medical Device Marketing Submissions"," Applying Human Factors and Usability Engineering to Medical Devices.") Based upon equivalence 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 be substantially equivalent to the legally marketed predicate devices. Therefore, the Subject device is substantially equivalent to the legally marketed predicate devices.