August 30, 2024

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

Re: K242249
Trade/Device Name: Conformity Stem Extension Line
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: July 30, 2024
Received: July 31, 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.

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,

Limin Sun -S

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)*

K242249

Device Name

Conformity Stem Extension Line

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.

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United Orthopedic Corporation

Conformity Stem Extension line

Contact Details

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

Device Name

Device Trade Name	Conformity Stem Extension line
Common Name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Classification Name	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented
Regulation Number	888.3353
Product Codes	LZO, MEH

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name	Product Code
K183312	Conformity stem, cementless	LZO, MEH

Device Description Summary	The "United" Conformity Stem cementless type (K183312) is designed for cementless use in hip arthroplasty. The Conformity Stem cementless type is a proximal trapezoid and distal quadrangular stem with 12/14 neck taper, 135° and 125° neck angle. It is manufactured from Ti-6Al-4V alloy, which conforms to ASTM F136-13 and the distal part of each femoral stem is coated with hydroxyapatite (HA) (ASTM F1185-03) to provide biological fixation. The "United" Conformity Stem cementless is available in various sizes with collarless and collared types to accommodate various hip surgical requirements. For the subject device, it's an extension line of the 510(K) cleared device Conformity Stem cementless type (K183312), which introduces two new variations: (1) Conformity stem,

	coxa vara, 125° STD, collared, #1-7; and (2) Conformity stem, short neck, #4-7. The indications, design rationales, materials, major manufacturing process, and sterilization method of the subject devices are identical to the 510(k) cleared Conformity Stem, cementless (K183312). 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, coxa vara, 125° STD, collared Conformity stem, coxa vara, 125° STD, collared is a new coxa vara type variation of 510(k) cleared Conformity stem, coxa vara (1110-52XX, K183312). The same as this 510(k) cleared device, it's also made of Ti-6Al-4V alloy (ASTM F136), and the distal part is coated with hydroxyapatite(HA) (ASTM F1185). In addition, the subject device is also a collared stem with a 125° neck angle. The only difference is the offset design. The subject device is standard offset, while the 510(k) cleared coxa vara collared stem (110-52XX) is high offset - Conformity Stem, short neck, #4-7 Conformity stem, short neck, #4-7 is an extension in terms of sizes to 510 (k) cleared device Conformity stem, short neck, #1-3 (K183312). The design, material, coating thickness, geometrical characteristics, neck angle (135°), and neck length (28.5mm) design are identical to 510 (k) cleared device Conformity Stem, short neck, #1-3 (K183312). The only different is the stem length sizes.
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.
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 is substantially equivalent to that of the predicate device Conformity stem, cementless (K183312) as the comparison given below. - Their intended use is the same. - The design, material, principle of operation, regulation number, product code, 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 offset specification and the stem length sizes. 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 - Range of Motion (ROM) evaluation per ISO 21535 - Neck fatigue analysis per ISO 7206-6 - Stem fatigue analysis per ISO 7206-4 No clinical tests were performed to support the safety and efficacy 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 Conformity extension line is considered substantially equivalent to the predicate devices (K183312).