January 3, 2020

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

Re: K191056
Trade/Device Name: Conformity stem, cemented
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI
Dated: December 4, 2019
Received: December 6, 2019

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 (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 located 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.

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

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

Vesa Vuniqi
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191056

Device Name
Conformity stem, cemented

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 dyplasia.
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 replacment or total hip replacement.
5. Certain cases of ankylosis.

Conformity stem, cemented 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

Submitter Information	
Name	United Orthopedic Corporation
Address	No 57, Park Ave 2, Science Park, Hsinchu City 30075, Taiwan
Phone Number	+886-3-5773351 ext. 2220
Fax Number	+886-3-577156
Name of Contact Person	Lois Ho, Regulatory Affairs Manager
Date prepared	April 15, 2019
Device Information	
Trade Name	Conformity stem, cemented
Common Name	Hip stem
Classification Name	Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350)
Device Class	Class II
Classification Panel	Orthopedics
Product Code	JDI, LZO, KWY
Predicate Device	"United" UCP stem (K152530)
Reference Device	"United" U2 Hip Stem (K003237)

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Device Description:

The "United" Conformity stem, cemented is a triple tapered, polished, collarless stem. It is available in various sizes with standard and high offset types to accommodate various hip surgical requirements. Conformity stem, cemented is manufactured from Co-Cr-Mo alloy which conform to ASTM F799-11 (Raw material: ASTM F1537-11/ISO 5832-12:2007). It is intended to be fixed only with the use of PMMA bone cement and should be used with "United" Cement restrictor.

For total hip arthroplasty, Conformity stem, cemented can be used with "United"acetabular liner, cup and femoral head. For bipolar hip replacement, Conformity stem, cemented can be used with "United" bipolar prosthesis.

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 dyplasia.
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.

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Comparison to Predicate Device:

The "United" Conformity stem, cemented is substantially equivalent to "United" UCP stem (K152530) in indication for use, material, manufacturing processes, design rationale and sterilization method.

The difference between the subject and the predicate devices is size distribution. The difference of size distribution does not affect the intended use of the device or alter the fundamental scientific technology of the device. As a result, Conformity stem, cemented is substantially equivalent to the predicate devices.

Performance Data:

- **Non-clinical Performance**

  The mechanical properties of this device have been evaluated, the taper of the subject device is identical to the predicate, and that finite element method (FEM) analysis was used to determine that no additional stem or neck fatigue testing was needed, and the ROM simulation results are substantially equivalent to the legally marketed device and meet the requirement of ISO 21535.

  In addition, bacterial endotoxin testing was conducted and met the endotoxin limit as specified in USP <161>.

  Performance data demonstrate the device is as safe and effective and is substantially equivalent to the legally marketed predicate devices.

- **Clinical Performance Data/Information**

  None provided as a basis for substantial equivalence.