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

August 8, 2019

Re: K183312
Trade/Device Name: Conformity Stem
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 2, 2019
Received: July 9, 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,

FOR 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)*

K183312

Device Name
Conformity Stem

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 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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510(k) Summary (K183312)

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	November 26, 2018
Device Information	
Trade Name	Conformity Stem
Common Name	Hip Stem
Regulation Name and Number	The device classification for **Conformity Stem** are "Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis" which are contained in the Code of Federal Regulation, under **21CFR 888.3353**. This falls under the Orthopedic Panel.
Device Class	Class II
Classification Panel	Orthopedics
Product Code	LZO, MEH
Predicate Device	"Depuy" Corail ATM Hip Prosthesis (K042992)
Reference Device	"United" U2 Hip Stem, HA/ Ti plasma spray (K003237) "United" UTF Stem reduced (K132207)

Device Description:

The "United" Conformity Stem cementless type is design 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 conform 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 subject device is available in various sizes with collarless and collared types to accommodate various hip surgical requirements.

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.

Conformity stem is for cementless use only.

Comparison of Technological Characteristics:

The features of the subject device are comparable to the predicate "Depuy" Corail ATM Hip Prosthesis (K042992) in terms of the indication for use, design rationale, materials, coating and sterilization method except for the size distribution. The differences in size distribution have been validated by stem fatigue testing, neck fatigue testing, range of

motion analysis and fretting corrosion analysis to demonstrate that the performance of subject device are substantially equivalence to the predicate device.

Performance Data:

- **Non-clinical Performance**

  Tests as follows were conducted to evaluate the safety and effectiveness of the subject device:

a. Stem fatigue test (ISO 7206-4)
b. Neck fatigue test (ISO 7206-6)
c. Range of Motion (ISO 21535)
d. Fretting Corrosion between Femoral Head and Stem (ASTM F1875 and ISO 7206-4)
e. Evaluation of Modified Surface Treatment (FDA Guidance - Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements)
f. Bacterial endotoxin testing was conducted and met the endotoxin limit as specified in USP <161>.

Performance data demonstrate the subject 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.

Substantial Equivalence Conclusion:

The subject device has the same intended use, materials, coating, sterilization methods, and similar design features as the predicate "Depuy" Corail ATM Hip Prosthesis (K042992). The performance results demonstrate that the subject device is as safe and effective as the legally marketed predicate device. Based on the information provided, the "United" Conformity Stem is considered substantially equivalence to the predicate device.