November 4, 2022

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

Re: K221675
Trade/Device Name: United U2 femoral head, 22mm delta ceramic head
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, KWY
Dated: October 4, 2022
Received: October 6, 2022

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221675

Device Name
United U2 femoral head, 22mm delta ceramic head

Indications for Use *(Describe)*
The device is indicated for use in hip arthroplasty in 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.

This device is a single use implant and intended for cementless use only except cemented stem which is designed for cemented use only.
In the USA: United U2 femoral head, 22mm delta ceramic head is only indicated for use with the hemi (bipolar) implant.

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

[as required by 21 CFR 807.92(c)]

Submitter information

Company Name:	United Orthopedic Corporation
Address	No 57, Park Ave 2, Science Park, Hsinchu City 30075, Taiwan
Telephone	+886-3-5773351 ext. 2220
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Contact Person	Lois Ho, Regulatory Affairs Manager
Email address	lois.ho@unitedorthopedic.com
Date of submission	November 4, 2022

Trade Name, Common Name, Classification

Device Common Name:	Ceramic femoral head prosthesis
Trade name:	United U2 femoral head, 22mm delta ceramic head
Submitter Establishment Number:	9681642
Classification Regulation Number:	21CFR 888.3358 21CFR 888.3390
Classification Panel:	Orthopedic
Product Code:	LPH KWY
Device Class:	Class II
Classification name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis

Predicate devices

Predicate	**510(k) Number**	**Manufacturer**
Primary Predicate		
U2 Femoral Head	K162957	United Orthopedic Corporation
Additional Predicate Devices		
United 36MM Ceramic Femoral Head, Delta	K112463	United Orthopedic Corporation
Ceramic Femoral Head	K103497	United Orthopedic Corporation
Klassic HD® Hip System	K180929	Total Joint Orthopedics (TJO)
U-MOTION II Acetabular System	K122185	United Orthopedic Corporation

Device description	The Subject device is a size extension to the previously cleared U2 Femoral Head (K162957). The design, manufacturer, materials, manufacturing progress, sterilization of this subject are identical or similar to its primary and additional predicates. Ceramic femoral head, delta, 22mm (Subject device) is manufactured from zirconia-toughened alumina ceramic is available in +1, +3 and +5 mm of neck length. This device is intended to articulate with U2 Bipolar Implant, 22mm I.D (K152439) and can be used in conjunction with United titanium Hip Stem. Hip Stem include HA/Ti Plasma Spray Stem (K003237), Ti porous coated Stem (K003237, K151316), Ti Press-fit Stem (K111546), Revision Hip Stem (K062978), UTS Stem (K172251), UTF Stem (K110245, K163193, K123550, K132207) and Conformity stem (K183312). The size extension does not affect the intended use or alter the fundamental scientific technology of the device. Surgical procedures with the use of the subject device shall be performed with the support of orthopedic instrumentation, to facilitate their proper insertion and removal from the patient.
Indications for use	The device is indicated for use in hip arthroplasty in 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. This device is a single use implant and intended for cementless use only except cemented stem which is designed for cemented use only. **In the USA: United U2 femoral head, 22mm delta ceramic head is only indicated for use with the hemi (bipolar) implant.**
Technological Characteristics	The Subject device fundamental scientific principles and technological characteristic, including: the intended use, material and general design, are the same as, or similar to, the primary predicate and the chosen additional predicate devices. Summary of the technological characteristics: ✓ *Intended use*: identical to primary predicate ✓ *Indications for Use, Anatomical sites, operating principles and conditions of use* are similar ✓ No new risks associated to the subject device compared to those of the predicate devices. ✓ Verification activities on subject device demonstrated substantially equivalent safety and effectiveness as compared to the predicate devices. ✓ *Material:* are identical to the additional ceramic predicates. ✓ *Geometry and size*: similar ✓ *Sterilization*: identical method as primary predicate. The *technological characteristics* of the subject device are substantially equivalent to the predicate device(s).

Performance Analysis	Based on the introduction of the subject device, safety and effectiveness were evaluated through the following engineering analysis to demonstrate substantial equivalence to the predicate devices: • Burst strength, fatigue and post-fatigue burst strength of femoral head from stem (ISO 7206-10 and ASTM F2345-03) • Pull-off strength of femoral head from stem (ASTM F2009) • Torque-off strength of femoral head from stem (ISO 7206-13) • Range of motion (ROM) (ISO 21535) • Pull-out strength of femoral head from bipolar head • Lever-out strength of femoral head from bipolar head Clinical testing was deemed not necessary for the subject device.
Conclusion	Engineering analyses showed that the subject components met the pre-determined acceptance criteria identified in the Design Control Activities, demonstrating that the subject component performs as safely and effectively compared to the predicate components, and is substantially equivalent to the legally marketed predicate devices