January 5, 2023

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

Re: K221149
Trade/Device Name: U-Motion II Acetabular System-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
Dated: December 7, 2022
Received: December 7, 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)*

K221149

Device Name
U-Motion II Acetabular System—Extension line

Indications for Use *(Describe)*

The device is used for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
4. Correction of functional deformity.
5. Treatment of nonunion femoral neck and trochanteric fracture of the proximal femur with head involvement that is unmanageable using other techniques.

This device is a single use implant and intended 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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510(K) SUMMARY
Traditional 510(k)

[as required by 21 CFR 807.92(c)]

Submitter information

Company Name:	United Orthopedic Corporation
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Contact Person	Lois Ho, Regulatory Affairs Manager
Email address	lois.ho@unitedorthopedic.com
Date of submission	April 18, 2022

Trade Name, Common Name, Classification

Device Common Name:	Acetabular Component
Trade name:	U-Motion II Acetabular System—Extension line
Submitter Establishment Number:	9681642
Classification Regulation Number:	21CFR 888.3353
Classification Panel:	Orthopedic
Product Code:	LZO
Device Class:	Class II
Classification name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Predicate devices

Product name	Manufacturer	510(k) Number
Primary Predicate		
U-Motion II Acetabular System	United Orthopedic Corporation	K122185
Additional Predicates		
U-Motion II PS^{+} Cup	United Orthopedic Corporation	K132455
U-Motion II Acetabular System—Additional sizes		K170089
E-XPE Acetabular Components and U-Motion II Acetabular Cup		K172833
U2 Hip System		K111546
Osteonics® HA Generation II Acetabular Component Sysrem	Osteonics Corporation	K983382

U-Motion II Acetabular System—Extension line *Traditional 510 (k)*

Device description	The subject device, U-Motion II Acetabular System—Extension line, is an extension in terms of additional size to the previously cleared U-Motion II Acetabular System (K122185, K132455, K170089 and K172833). The subject device includes two components: U-Motion II Cup and U-Motion II XPE Cup liner. The indication, design rationale, material, major manufacture process and sterilization method of these two components are identical to the cleared U-Motion II Cup (K122185, K132455, K170089, and K172833) and U-Motion II XPE Cup Liner (K122185 and K170089), except for the dimension. ● U-Motion II Cup The cleared U-Motion II Cup is available from 44 through 80 mm outer diameter (O.D.) in 2 mm increments. The subject U-Motion II Cup is available in 48 mm O.D. and 54 mm O.D. and the compatible liner diameter is 36 mm and 40 mm, respectively, which is larger than the cleared cups. It is designed to only be compatible with the subject cup liner. ● U-Motion II XPE Cup Liner The cleared U-Motion II XPE Cup Liner is available in 28 mm, 32 mm, 36 mm, and 40 mm inner diameter (I.D.). The subject XPE Cup Liner is available in 36 mm I.D. and 40 mm I.D., and is compatible with the subject 48 mm O.D. cup. and 54 mm O.D. cup, respectively.
Indications for use	The device is used for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis. 2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure. 3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results. 4. Correction of functional deformity. 5. Treatment of nonunion femoral neck and trochanteric fracture of the proximal femur with head involvement that is unmanageable using other techniques. This device is a single use implant and intended for cementless use only.
Technological Characteristics	The Subject device fundamental scientific principles and technological characteristics, including: the intended use, material and general design, are the same as, or similar to, the primary predicate and the chosen additional predicate/reference devices. Summary of the technological characteristics: ✓ *Intended use*: identical ✓ *Indications for Use, Anatomical sites, operating principles and conditions of use* are identical ✓ No new risks associated to the Subject device compared to those of the predicate devices. ✓ Verification activities on subject devices demonstrated equivalent safety and effectiveness as compared to the predicate devices. ✓ *Material:* are identical to the primary predicate.

	✓ *Geometry and size*: thickness of the subject liner is the worst-case and has been demonstrated equivalent safety and effectiveness as compared to the predicate devices. ✓ *Sterilization*: identical method as predicates. The *technological characteristics* of the Subject device are substantially equivalent to the predicate device(s).
Performance Analysis	Based on the modification items of the design rationale of the Subject device, the following tests were conducted to evaluate the safety and effectiveness of the subjected device, and the test results indicated that this device is safe and effective. • Impingement analysis • Range of motion • Jumping distance analysis • Wear simulation test • Locking strength test • Cup deformation test • Cup fatigue test
Conclusion	Based upon equivalences 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 to be safe and effective and to perform equivalently as compared to the legally marketed predicate devices. Therefore, the Subject devices are substantially equivalent to the legally marketed predicate devices.