January 6, 2023

Depuy Ireland UC
Paige Myers
Regulatory Affairs Specialist
Loughbeg, Ringaskiddy
Cork
Ireland

Re: K222296
Trade/Device Name: ARTICUL/EZE Ceramic Heads
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 2, 2022
Received: December 2, 2022

Dear Paige Myers:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K222296

Device Name
ARTICUL/EZE Ceramic Femoral Heads

Indications for Use *(Describe)*

INDICATIONS FOR USE

Total hip replacement is indicated in 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 arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

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.

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510(K) SUMMARY
(As required by 21 CFR 807.92 and 21 CFR 807.93)

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Establishment Registration Number	3015516266
Name of contact person	Paige Myers
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Alternate Contact Person	Clare Hill
Alternate Contact E-Mail	Chill7@its.jnj.com
Alternate Contact Phone	+44 7795 389956 (UK time zone)
Date prepared	6 January 2023
Name of device	
Trade or proprietary name	ARTICUL/EZE Ceramic Heads
Common or usual name	Ceramic femoral ball prosthesis
Classification name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3353
Product Code(s)	LZO
Legally marketed device(s) to which equivalence is claimed	Primary Predicate Device: DEPUY CERAMIC FEMORAL HEADS: K031803 Secondary Predicate Device: ARTICUL/EZE FEMORAL HEADS: K980513 Reference Device: ICONACY I-Hip K151307
Reason for 510(k) submission	The purpose of this 510K submission is to obtain market clearance for ARTICUL/EZE Ceramic Heads
Device description	The ARTICUL/EZE Ceramic Heads are a zirconia toughened alumina composite ceramic femoral head designed to be used as one component of a

	system of prostheses in hip arthroplasty. The femoral heads are available in a wide range of outer diameter sizes and offsets.
Intended use of the device	Total hip arthroplasty
Indications for use	Total hip replacement is indicated in 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 arthroplasty, or total hip replacement. 5. Certain cases of ankylosis.
Performance Testing	The ARTICUL/EZE Ceramic Heads were tested to demonstrate the substantial equivalence to the identified predicate devices. Testing and analyses included: • Static Compression (Burst) testing per ISO 7206-10:2018 • Axial Pull-off testing per ISO 7206-10:2018 • Torque-off testing per ISO 7206-13:2016 • Wear testing per ISO 14242-1:2014 • Material Wear after Aging testing per ISO 6474-2:2019 • Impact strength per ISO 11491:2017 • MRI Safety Evaluation testing per ISO 14630:2012 • Biocompatibility testing per 10993-1:2018 • Bacterial endotoxin per ANSI/AAMI ST 72:2019

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE				
Characteristics	**Subject Device: ARTICUL/EZE Ceramic Heads**	**Primary Predicate Device: DEPUY CERAMIC FEMORAL HEADS (K031803)**	**Secondary Predicate Device: ARTICUL/EZE COCR FEMORAL HEADS (K980513)**	**Reference Device: ICONACY I-Hip (K151307)**
Intended Use	Same as primary predicate device	Intended for use in total hip arthroplasty	Same as primary predicate device	Same as primary predicate device
Indications for Use	Same as primary predicate device	Total hip replacement is indicated in 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 arthroplasty, or total hip replacement. 5. Certain cases of ankylosis.	Total hip replacement is indicated in the following conditions: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, or rheumatoid arthritis 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 arthroplasty, or total hip replacement. 5. Certain cases of ankylosis.	1. A severely painful and/or disabled hip joint as a result of 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 arthroplasty, or total hip replacement. 5. Certain cases of ankylosis 6. Nonunions, correction of functional deformity, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Material	Cerasurf-w, a Zirconia-toughened Alumina Ceramic (ZTA) (ISO 6474-2:2019)	CeramTec BIOLOX® *delta*, a Zirconia-toughened Alumina Ceramic (ZTA)(ISO 6474-2:2019)	CoCrMo (ASTM F1537-11)	Ceramic heads: Cerasurf-p, a Zirconia-toughened Alumina Ceramic (ZTA)(ISO 6474-2:2019)
Outer Diameter Sizes	Same as secondary predicate device	28mm, 32mm, 36mm	22.225mm, 28mm, 32mm, 36mm, 40mm	28mm, 32mm, 36mm
Taper	Same as primary predicate device	12/14 ARTICUL/EZE taper	Same as primary predicate device	12/14 taper
Offsets	Same as secondary predicate device	28mm: +1.5, +5, +8.5 32mm: +1, +5, +9 36mm: +1.5, +5, +8.5, +12	22.225mm: +4, +7 28mm: +1.5, +5, +8.5, 32mm: +1, +5, +9 36mm: -2, +1.5, +5, +8.5, +12 40mm: -2, +1.5, +5, +8.5, +12	28mm: -4, +0, +4 32mm: -4, +0, +4, +7 36mm: -4, +0, +4, +8

The subject device has the same intended use and indications as both the primary and secondary predicate devices. They are all femoral heads that are intended to replace diseased or broken femoral head and neck bone in combination with a femoral stem prosthesis. They all replace the native femoral head and are assembled intraoperatively with a compatible femoral stem to articulate against an acetabular component. The subject devices and both predicate devices are intended for total hip arthroplasty and are compatible with 12/14 ARTICUL/EZE Tapers. The subject device and the secondary predicate device have identical sizes and offsets. The subject device and both predicate devices have the same method of sterilization, Sterility Assurance Level (SAL), packaging materials, and shelf-life. The ARTICUL/EZE Ceramic Heads are similar to the predicate DEPUY CERAMIC FEMORAL HEADS (K031803) and the predicate ARTICUL/EZE COCR FEMORAL HEADS (K980513) in design. Both the subject device, the primary predicate, and the reference device ICONACY I-Hip (K151307) are made of a zirconia toughened alumina (ZTA) ceramic that is compliant to ISO 6474-2:2019.
The reference device was used to demonstrate biological safety and equivalence for the manufacturing process and raw material of the subject device.

Results of performance testing and analyses demonstrate that the ARTICUL/EZE Ceramic Heads perform as well as the predicate devices.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

No clinical tests were conducted to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The subject ARTICUL/EZE Ceramic Heads are substantially equivalent to the predicate DEPUY CERAMIC FEMORAL HEADS (K031803) and ARTICUL/EZE COCR FEMORAL HEADS (K980513)