October 21, 2022

DePuy Ireland UC
Jennifer Hill
Regulatory Project Leader, Regulatory Affairs
Loughbeg, Ringaskiddy
Co. Cork Munster, P43 ED82,
IRELAND

Re: K221462
Trade/Device Name: DePuy Reclaim Monobloc Revision Femoral 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
Dated: July 21, 2022
Received: July 25, 2022

Dear Jennifer Hill:

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, 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)*
K221462

Device Name
DePuy Reclaim Monobloc Revision Femoral Stem

Indications for Use *(Describe)*

The DePuy RECLAIM Monobloc Revision Femoral Stem is indicated for cementless use in the treatment of failed previous hip surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement.

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

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Co. Cork Munster, P43 ED82, IRELAND
Phone number	(+44)7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	20 October 2022
Name of device	
Trade or proprietary name	DePuy Reclaim Monobloc Revision Femoral Stem
Common or usual name	Hip Stem Prosthesis
Classification name	**21 CFR 888.3353:** Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. (LZO)
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3353
Product Code(s)	**LZO**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented.
Legally marketed device(s) to which equivalence is claimed	DePuy Reclaim Modular (K102080)
Reason for 510(k) submission	The purpose of this submission is for the addition of a new femoral stem option to the DePuy Hip Revision portfolio.
Device description	The Subject Devices DePuy Reclaim Monobloc Femoral Stems are revision implants that are intended to treat patients with prior failed hip replacement devices. They are made of Ti6Al4V alloy and present a grit-blasted tapered fluted intramedullary region with splines that are intended to be in interference of the previously reamed femoral cavity and in contact with the cortical bone in the canal in an uncemented use.

	The design of the Subject Device extramedullary region is based on that of the Predicate Reclaim Modular stem implants which were cleared by the FDA via K102080 in 2010. The extramedullary region has standard and high offset options on a polished neck, with a 12/14 AMT trunnion. The Subject Devices are intended to be inserted into the femoral canal using the Reclaim Monobloc Inserter Instruments. With the exception of the Subject Device being a one-piece implant versus the Predicate two-piece modular implant, resulting in fewer theoretically possible construct lengths, and the addition of the secondary splines, the Subject and Predicate Devices are identical in intended use, indications for use, materials, sterilization method, and fixation method. The non-modular design, and the addition of the secondary splines do not impact the safety or effectiveness of the Subject Device as compared to the Predicate. This 510(k) also includes sterilization instrument trays, that, according to FDA guidance document *"Medical Device Accessories – Describing Accessories and Classification Pathways, Guidance for Industry and Food and Drug Administration Staff,"* issued on December 20, 2017, requires clearance under the same product codes as the Subject Device.
Intended use of the device	**Total Hip Arthroplasty** Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.
Indications for use	The DePuy RECLAIM Monobloc Revision Femoral Stem is indicated for cementless use in the treatment of failed previous hip surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement.

The Subject Device, DePuy Reclaim Monobloc Revision Femoral Stem is substantially equivalent to the Predicate Device, DePuy Reclaim Modular Revision Hip System (K102080) in intended use, design, material, and fixation. The Subject and Predicate Devices are intended for total hip arthroplasty, are made of the same Ti_6Al_4V titanium alloy, are intended for uncemented use and present a grit-blasted tapered fluted intramedullary region with splines that are intended to be in interference of the previously reamed femoral cavity and contacting the cortical bone in the canal.

Differences include the type of modularity and number of splines — the Subject Device is a non-modular, singular stem, whereas the Predicate Device is a modular, two-part system stem. The Subject Device also has additional splines with a taper profile along the stem length which provide greater axial stability. The modification from a modular to singular monobloc device and addition of tapered splines has shown to have no impact on the safety or effectiveness of the Subject Device compared to the Predicate Device.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The following tests were performed on the Subject Devices, Reclaim Monobloc Revision Femoral Stems, to demonstrate substantial equivalence of safety and effectiveness as compared to the Predicate Device. All testing was performed on final sterile devices:

Performance Bench Test Results	
Test	**Conclusion**
Stem Fatigue Design Verification (ISO 7206-4)	Pass
Neck Fatigue Design Verification (ISO 7206-6)	Pass
Range of Motion (ISO 21535:2007 Annex A)	Pass
Trays Drop and Mating Part Test	Pass

Biocompatibility Results	
Test	**Conclusion**
Monobloc Stem Biocompatibility Testing	Pass
Instrument Trays Biocompatibility Evaluation	Pass

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

No clinical studies were performed for performance testing as appropriate verification and validation of the Subject Device was achieved based on the comparison to the Predicate Device and from the results of the Bench testing and Biocompatibility testing.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

With the exception of the Subject Device being a one-piece implant versus the Predicate two-piece modular implant, resulting in fewer theoretically possible construct lengths, and the addition of the secondary splines, the Subject and Predicate Devices are identical in intended use, indications for use, materials, sterilization method, and fixation method. The non-modular design, and the addition of the secondary splines do not impact the safety or effectiveness of the Subject Device as compared to the Predicate.