May 23, 2025

DePuy Ireland UC
Robin Layton
Regulatory Affairs Project Leader
Loughbeg
Ringaskiddy
Co. Cork,
Ireland

Re: K251292
Trade/Device Name: 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: April 24, 2025
Received: April 25, 2025

Dear Robin Layton:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

RYAN TROMBETTA -S

For: 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251292

Please provide the device trade name(s).

RECLAIM Monobloc Revision Femoral Stem

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Co. Cork, IRELAND
Establishment Registration Number	3015516266
Name of contact person	Robin Layton
e-mail address	rlayton@its.jnj.com DePuySynthesJointsRegulatoryAffairs@its.jnj.com
Alternative contact person	Clare Hill
e-mail address	Chill7@its.jnj.com
Work mobile	(+44) 7795 389956 (UK time zone)
Date prepared	25th April 2024
Name of device	
Trade or proprietary name	RECLAIM Monobloc Revision Femoral Stem
Common or usual name	Total Hip Arthroplasty Prosthesis
Classification name	21 CFR 888.3353: 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 – RECLAIM Monobloc Revision Femoral Stem – K221462 Additional Predicate – RECLAIM Monobloc Revision Femoral Stem – K231873
Reason for 510(k) submission	The purpose of this 510(k) submission is to expand the scope of the legally marketed RECLAIM Monobloc Revision Femoral Stem to include additional sizes.
Device description	The subject devices in this line extension to the RECLAIM Monobloc Revision Femoral Stem (previously cleared through Primary Predicate 510(k) K221462 and with MRI Conditional status cleared through 510(k) K231873) include four new Standard length RECLAIM Monobloc Revision Femoral Stems and twenty-three new Short length RECLAIM Monobloc Revision Femoral Stems.

	The line extension will extend the DePuy RECLAIM Monobloc Revision Femoral Stems portfolio by twenty-seven product codes. The Subject Device RECLAIM Monobloc Revision 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.
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.
Performance Testing	The RECLAIM Monobloc Revision Femoral Stem subject devices were compared to the predicate devices and assessed for worst-case. Testing was only conducted in situations where a new worst-case was identified No new worst-case was identified for the following: • Neck Fatigue • MRI Safety The RECLAIM Monobloc Revision Femoral Stem subject devices were tested to demonstrate substantial equivalence to the identified predicate devices. Testing and analyses were completed for: • Range of motion • Stem Fatigue
Conclusions Drawn from Performance Data	The RECLAIM Monobloc Revision Femoral Stem is substantially equivalent to the identified predicate with respect to intended use, indications, materials, geometry, range of sizes, and method of fixation. Results of performance testing and analyses demonstrate that the RECLAIM Monobloc Revision Femoral Stem performs as well as the predicate device.