January 19, 2024

DePuy Ireland UC
% Jennifer Hill
Regulatory Affairs Project Leader
DePuy Synthes
3 Main Street
Ringaskiddy, Loughbeg
Ireland

Re: K231873
Trade/Device Name: DePuy SUMMIT Porocoat Hip Prosthesis - MR Conditional, DePuy SUMMIT DuoFix Hip Prosthesis - MR Conditional, DePuy SUMMIT Cemented Hip Prosthesis - MR Conditional, DePuy SUMMIT FX Cemented Hip Prosthesis - MR Conditional, DePuy SUMMIT Basic Press-Fit Hip Prosthesis - MR Conditional
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: MEH, LPH, JDI, LWJ, LZO, KWL, KWY, LZY, HWC, LRN
Dated: December 14, 2023
Received: December 14, 2023

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 (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.

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,

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

FDA IFU FORMS 3381

HIP STEMS
FDA IFU FORMS 3381

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)*
K942370/K961619

Device Name
ENDURANCE CEMENTED HIP PROSTHESIS, ENDURANCE CALCAR PROSTHESIS

Indications for Use *(Describe)*

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K982918/K013350/K042959/K082239/K220216/K093736/K851422/K910664/K934412/K961939/K903084/K073570

Device Name
C-STEM SYSTEM, C-STEM AMT HIP PROSTHESIS, CORAIL REVISION HIP PROSTHESIS, S-ROM FEMORAL TOTA HIP SYSTEM, S-ROM TOTAL HIP SYSTEM, S-ROM COATED ZT PROXIMAL HIP SYSTEM, S-ROM FEMORAL HIP STEM, MODULAR CATHCART FRACTURE SYSTEM, TRI-LOCK BPS

Indications for Use *(Describe)*

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.

The DePuy® C-Stem AMT Hip Stem is indicated for cemented use only.

HA-coated stems of the CORAIL Hip System are indicated 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)

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510(k) Number *(if known)*
K102080/K221462

Device Name
RECLAIM MODULAR REVISION HIP SYSTEM, RECLAIM MONOBLOC REVISION HIP SYSTEM

Indications for Use *(Describe)*

The DePuy RECLAIM 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)

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K953703/K030979/K060581

Device Name
VISION SOLUTION HIP PROSTHESIS, SOLUTION SYSTEM HIP PROSTHESIS

Indications for Use *(Describe)*

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.

The Solution Hip Stem is indicated for cementless use and fixation by biological tissue ingrowth into the porous coating as well as cemented use and fixation in which the porous coating serves as a means to augment the fixation of the prosthesis to the bone cement.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
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510(k) Number *(if known)*
K001991/K011489/K013352/K023453/K030122/K202472/K210581/K211657/K192946

Device Name
SUMMIT POROCOAT, SUMMIT DUOFIX, SUMMIT CEMENTED, SUMMIT FX CEMENTED, SUMMIT BASIC PRESS-FIT HIP PROSTHESIS, ACTIS DUOFIX, ACTIS DUOFIX COLLARLESS HIP PROSTHESIS, EMPHASYS FEMORAL STEM, CORAIL AMT HIP PROSTHESIS

Indications for Use *(Describe)*

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.

Hemi hip replacement is indicated in the following conditions:

1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation.
2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation.
3. Avascular necrosis of the femoral head.
4. Non-union of femoral neck fractures.
5. Certain high subcapital and femoral neck fractures in the elderly.
6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement.
7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

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)

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ACETABULAR PRODUCTS
FDA IFU FORMS 3381

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)*
K203532

Device Name
BI-MENTUM ALTRX DUAL MOBILITY LINERS

Indications for Use *(Describe)*

BI-MENTUM™ ALTRX® Dual Mobility Liner is indicated for total hip replacement in the following conditions:
1. Osteoarthritis
2. Femoral neck fracture
3. Dislocation risk
4. Osteonecrosis of the femoral head
5. Revision procedures where other treatments or devices have failed are if bone reconstruction so permits

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200854

Device Name
PINNACLE DUAL MOBILITY LINER

Indications for Use *(Describe)*

Total hip replacement or hip arthroplasty is indicated in the following conditions:
1. A severely painful and/or disabled joint (typically due to non inflammatory degenerative joint disease).
2. Failed previous hip surgery.
3. Dislocation risks.

PINNACLE Dual Mobility Metal Liners and Porous-coated PINNACLE Acetabular Cups are intended for cementless applications.

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)

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Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K072963, K102423, K132959, K090998, K093646, K033273, K001534

Device Name
PINNACLE ALTRX ACETABULAR LINERS, PINNACLE 100 GRIPTION CUPS, PINNACLE GRIPTION CUPS, PINNACLE ACETABULAR ENHANCED STABILITY LINERS, PINNACLE ACETABULAR SYSTEM

Indications for Use *(Describe)*

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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K033338, K192919, K040544, K951674, K961186, K994415, K010171, K863184, K221636

Device Name
PINNACLE REVISION SYSTEM, PINNACLE DUOFIX HA ACETABULAR CUP, DURALOC OPTION CUP SYSTEM, DURALOC 100C CUP, DURALOC CEMENTLESS CUP SYSTEM, MARATHON CROSS-LINKED POLYETHYLENE CUP LINERS, 36MM MARATHON LINERS, PROFILE ACETABULUM PROSTHESIS, EMPHASYS ACETABULAR SYSTEM

Indications for Use *(Describe)*

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)

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FEMORAL HEADS
FDA IFU FORMS 3381

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K860701, K880269, K883460, K060031, K980513, K120599, K222296, K011533, K031803, K062748, K071830, K871867

Device Name
HPS FEMORAL BALL HEADS, TOTAL HIP BALL FEMORAL HEADS, ARTICUL/EZE FEMORAL HEADS, MODULAR M HEADS, 36mm FEMORAL HEADS, ARTICUL/EZE CERAMIC HEADS, DELTA CERAMIC FEMORAL HEADS, DELTA TS CERAMIC FEMORAL HEADS, ELITE FEMORAL HEADS

Indications for Use *(Describe)*

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)

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See PRA Statement below.

510(k) Number *(if known)*
K812672

Device Name
SELF-CENTERING HIP

Indications for Use *(Describe)*

Self-Centering hip arthroplasty is indicated in the following conditions:

1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation.
2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation.
3. Avascular necrosis of the femoral head.
4. Non-union of femoral neck fractures.
5. Certain high subcapital and femoral neck fractures in the elderly.
6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement.
7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

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)

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See PRA Statement below.

510(k) Number *(if known)*
K851422/K920317

Device Name
S-ROM FEMORAL HEADS

Indications for Use *(Describe)*

INDICATIONS – TOTAL HIP PROSTHESIS
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. Certain cases of ankylosis.

INDICATIONS – HEMI-HIP PROSTHESIS
Hemi-hip arthroplasty is indicated in the following conditions:
1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation.
2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation.
3. Avascular necrosis of the femoral head.
4. Non-union of femoral neck fractures.
5. Certain high subcapital and femoral neck fractures in the elderly.
6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement.
7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

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)

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COMPONENTS
FDA IFU FORMS 3381

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)*
K861979, K970929, K983014, K123924

Device Name

DEPUY 5.0MM TAPERED HEAD PERIPHERAL SCREW, LOW PROFILE BONE SCREW, ACETABULAR SYSTEM SCREWS, GRIPTION TF 5.5mm LOCKING SCREWS

Indications for Use *(Describe)*
The DePuy Screws are indicated for use in primary or revision hip surgery for total hip replacement in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoir 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)

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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)*
K963309

Device Name

DEPUY APEX HOLE ELIMINATOR PS

Indications for Use *(Describe)*

The Apex Hole Eliminator PS is a threaded plug intended to close the apical hole of the Duraloc series two-piece (metal shell and UHMWPe liner) acetabular cups. It is intended for use in Duraloc cups implanted with or without bone cement.

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)

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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)*
K971682

Device Name

DEPUY J-FX CERCLAGE SYSTEM

Indications for Use *(Describe)*

The J-Fx Cerclage System is indicated for use as a cerclage fixation device in general orthopaedic repairs. These include procedures such as: reinforcement of bone; reattachment of the greater trochanter; fixation of long bone fractures with grafting; and fixation of patellar fractures.

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)

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K100391

Device Name

DEPUY GRIPTION TF CONES & HIP AUGMENTS

Indications for Use *(Describe)*

The DePuy Gription TF Acetabular Augments, Buttresses and Shims are indicated for use in total hip replacement in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoir 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.

The porous Gription TF titanium acetabular augment is affixed to the mating acetabular cup using bone cement or mechanical screw fixation. The assembled porous titanium augment is intended for cemented or cementless use.

The porous Gription TF titanium shim is affixed to the mating buttress using bone cement. This porous Gription TF titanium buttress is affixed to the mating acetabular cup using bone cement. The assembled buttress/acetabular cup construct is intended for cemented or cementless use.

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)

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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)*
K800894

Device Name

DEPUY CEMENT RESTRICTOR

Indications for Use *(Describe)*

The UHMWPe cement restrictor is intended for use in cemented total and hemiarthroplasty procedures to restrict distal flow of bone cement in the femoral medullary cavity.

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)

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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)*
K871510

Device Name

DEPUY MODIFIED PROFILE HIP PMMA CEMENT SPACER

Indications for Use *(Describe)*

The Modified Profile Hip PMMA Spacer is indicated for use in cemented 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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K963206, K951000

Device Name

DEPUY S-ROM HIP SYSTEM LOCKING PLUG, S-ROM SCREWS

Indications for Use *(Describe)*

Total hip arthroplasty is indicated for total hip replacement 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)

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510k
Summaries

HIP STEMS
510k Summaries

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	C-STEM™ System C-STEM™ AMT Hip Prosthesis CORAIL™ Revision Hip Prosthesis S-ROM™ Femoral Total Hip System S-ROM™ Total Hip System S-ROM™ Coated ZT Proximal Hip System S-ROM™ Femoral Hip Stem (Sizes 12x06x115 & 12x07x115) Tri-Lock Bone Preservation Stem
Common or usual name	Total Hip Joint Replacement Prosthesis

	Uncemented Hip Prosthesis Femoral Prosthesis Porous Coated Hip Prosthesis
Classification name	**21 CFR 888.3350**: Hip joint metal/polymer semi-constrained cemented prosthesis. **21 CFR 888.3353**: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. **21 CFR 888.3358**: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. **21 CFR 888.3360:** Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis. **21 CFR 888.3390:** Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3350 Class II – 21 CFR 888.3353 Class II – 21 CFR 888.3358 Class II – 21 CFR 888.3360 Class II – 21 CFR 888.3390
Product Code(s)	**JDI**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented **LZO**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented **LPH**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous uncemented **MEH**: Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium Phosphate **KWL**: Prosthesis, Hip, Hemi-, Femoral, Metal

	KWY: Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented **LWJ**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K982918/K013350 - DePuy C-STEM™ System K042959/K082239/K220216 – DePuy C-STEM™ AMT Hip Prosthesis K093736 – DePuy CORAIL™ Revision Hip Prosthesis K851422 – DePuy S-ROM™ Femoral Total Hip System K910664 - DePuy S-ROM™ Total Hip System K934412 - DePuy S-ROM™ Coated ZT Proximal Hip System K961939 - DePuy S-ROM™ Femoral Hip Stem (Sizes 12x06x115 & 12x07x115) K073570 - DePuy Tri-Lock Bone Preservation Stem
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code

	with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	**C-STEM Product Family** The DePuy C-STEM™ System includes stainless steel femoral stems, a gelatin end cap and PMMA centralizers. The C-STEM™ is a collarless, slim profiled, triple tapered and overall polished stem that is available in four stem designs. The four stem designs are: a CDH stem available in one size; a primary stem available in eight sizes (1,2,3,4,5,6,7,8); a high offset stem available in three sizes (3,4 and 5); and a revision stem available in three sizes (4,6 and 8) each of which is available in two lengths (200mm and 240mm). The DePuy C-STEM™ AMT hip is a collarless, tapered, press-fit femoral stem. It is manufactured from wrought stainless steel (Ortron 90® conforming to ISO 5832-9) and is polished overall. The stem is offered in 7 sizes, with each body size having either a standard or high offset. It may be used with commercially available modular femoral heads, either metal or ceramic, to form the femoral component of a total hip prosthesis. Accessory items include previously cleared cement restrictors and centralizers. **CORAIL Product Family** The DePuy CORAIL™ Revision hip stems are manufactured from forged titanium alloy (Ti_6Al_4V) and plasma-sprayed with a hydroxyapatite (HA) coating for bone fixation. The stems consists of a wide range of stem neck designs and sizes allowing an accurate anatomical match for each patient. Corail stems are available with or without a collar, with various neck angles, and with various neck offsets. **S-ROM Product Family**

	The DePuy S-ROM™ Total Hip System is a modular system for use in total hip replacement. The system includes several types of femoral stems, various types of proximal sleeves, cobalt-chromium and ceramic femoral heads, various types of acetabular shells, acetabular liners, trochanter screws, trochanter washers, peripheral screws, locking pins, and apical hole plugs, all distributed by representatives of DePuy. The femoral stem uses a nominal 11-13 Morse-type taper and is composed of titanium alloy (Ti-AL6-V4). It is supplied in a variety of lengths and diameters. It is also available with a variety of neck lengths and in several different neck designs, as follows: a standard neck design, a standard neck design with increased offsets, a calcar replacement design and a calcar replacement design with increased offsets. The stem is compatible with S-ROM Total Hip System femoral heads, both cobalt chromium alloy (Co-Cr-Mo) and ceramic. The DePuy S-ROM™ Coated ZT Proximal Hip Stem is a modular hip prosthesis system which achieves proper fit and fill through its modularity. The femoral side achieves this through the use of a stem/sleeve (collar) combination which is available in a variety of stem/sleeve/cone sizes as currently marketed for the ZT sleeve. The basic ZT sleeve is an elliptical Ti_6Al_4V non-cemented proximal femoral sleeve the shape of which matches the anatomy (contour of the bone). There is a 3 per side taper conical fit of the sleeve on the stem. It's exterior is stepped to maximise compressive stresses and minimize hoop and shear stress. The DePuy S-ROM™ Femoral Hip Stems (Sizes 12x06x115 and 12x07x115) are manufactured from Ti_6Al_4V, the same material used to manufacture the S-RO femoral hip stems in the larger sizes and that has been used in orthopaedic implants for many years with established clinical success. The S-ROM Femoral Hip Stems are anatomically shaped with flutes and a coronal slot in the distal portion of the stem. The size 12x06x115 and 12x07x115 stems, as well as the larger size S-ROM femoral hip stems, can be used in either the right or left hip. **Tri-Lock BPS** The Tri-Lock Bone Preservation Stem (BPS) is part of a modular prosthesis system for use in total hip replacement. It mates with DePuy femoral heads and articulates with DePuy acetabular cups.

	The Tri-Lock BPS has a flat, tapered stem design, with a modular head, 12/14 taper, proximal ML geometry. It is proximally coated with porous coating, manufactured of titanium alloy conforming to ASTM F-620. The Tri-Lock BPS utilizes the neck geometry (130° neck angle) of the Summit stem cleared in K001991. The stem comes in thirteen sizes, with each size available in both high and standard offsets via direct lateralization.
Intended use of the device	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	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. The DePuy C-STEM™ Hip Stems are indicated for cemented use only. HA-coated stems of the CORAIL™ Hip System are indicated for cementless use only.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels

	and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the DePuy C-STEM™, CORAIL™ and S-ROM™ Hip Prosthesis in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	EMPHASYS™ Femoral Stem
Common or usual name	Total or Hemi-Hip Arthroplasty Prosthesis
Classification name	**21 CFR 888.3353**: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. **21 CFR 888.3360**: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis. **21 CFR 888.3390**: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.
Class	II

Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3353 Class II – 21 CFR 888.3360 Class II – 21 CFR 888.3390
Product Code(s)	**MEH**: Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium Phosphate. **LZO**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented. **KWL**: Prosthesis, Hip, Hemi-, Femoral, Metal. **KWY**: Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented.
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K211657 - DePuy EMPHASYS™ Femoral Stem
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.

Device description	The DePuy EMPHASYS™ Femoral Stem prosthesis includes HA-coated proximal trapezoidal and distal quadrangular stems with tapered sides and proximal horizontal and distal vertical grooves in four configurations (Collared Standard Offset, Collarless Standard Offset, Collared High Offset and Collarless High Offset).
Intended use of the device	Total and hemi-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. Total or hemi-hip arthroplasty may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total or hemi-hip replacement outweighs the risks associated with the age of the patient and if limited demands regarding activity and hip joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in hip mobility may lead to an expectation of significant improvement in the quality of their lives.
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. Hemi-hip replacement is indicated in the following conditions: 1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation.

	2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation. 3. Avascular necrosis of the femoral head. 4. Non-union of femoral neck fractures. 5. Certain high subcaptial and femoral neck fractures in the elderly. 6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement. 7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the DePuy EMPHASYS™ Femoral Stem in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21)

	• Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	Endurance Cemented Hip Prosthesis Endurance Calcar Hip Prosthesis
Common or usual name	Hip Prosthesis
Classification name	**21 CFR 888.3350**: Hip joint metal/polymer semi-constrained cemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3350
Product Code(s)	**JDI**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented

Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K942370 – DePuy Endurance Cemented Hip Prosthesis K961619 - DePuy Endurance Calcar Hip Prosthesis
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	**DePuy Endurance** The DePuy Endurance Cemented Hip Prosthesis is manufactured from ASTM F-799 Forged Cobalt-Chromium-Molybdenum alloy. The stem has a proximal anterior/posterior flange which is intended to compress the bone cement during insertion, center the stem proximally, transfer loads to the cement proximally, enhance torsional stability and resist subsidence. The DePuy Cemented Hip Prosthesis has broadly raised edges and corners to prevent creating stress concentrations in the cement mantle.

	DePuy Endurance Calcar The Endurance Calcar Hip Prosthesis is available in one size and two stem lengths. The Endurance Calcar stems do not have a collar but do have a 2.25cm calcar platform which is used to seat the implant. The Endurance Calcar is designed for use with cement and so has no sharp corners and broadly radiused medial and lateral curves.
Intended use of the device	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	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.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding

	updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the DePuy Endurance and DePuy Endurance Calcar Cemented Hip Prosthesis in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	Modular Cathcart Fracture System
Common or usual name	Hip Prosthesis
Classification name	**21 CFR 888.3360** - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3360
Product Code(s)	**LWJ**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented

Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K903084 - Modular Cathcart Fracture System
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	The Modular Cathcart System consists of two components which together allow the surgeon to vary the neck length on existing hip implants. The Modular Sleeve Spacer is a double tapered conical section which will be press fit onto the neck of hip implants with neck taper outer diameters of 13.7mm or 16.0mm. For each sleeve size, there are three outer taper dimensions referred to as 0mm, +5mm and +10mm. These numbers indicate the extension added to the implant neck length by that corresponding taper. The proximal outer diameter is the same for all three extensions and the different extension lengths come from the different distances at which the taper angle originates on the sleeve. The Cathcart balls, produced from cast Orthochrome, are designed to mate with the sleeves in press-fit applications. All balls have the same inner taper dimensions to fit all sleeve tapers. Neck length adjustment is achieved by variations in the external and internal taper dimensions of the

	sleeve taper. The Cathcart (out-of-round) shaped ball will be available in outer diameter sizes ranging from 41-60mm. These sizes allow for optimal sizing and revision fit.
Intended use of the device	The Modular Cathcart Fracture System is intended for use with existing hip stems as the femoral neck and head prosthesis in total hip arthroplasty or as an endoprosthesis.
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.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries.

	There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the Modular Cathcart Fracture System in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	RECLAIM™ Revision Hip System 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.
Class	II

Classification panel	87 Orthopedics
Regulation	Class II – 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	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K221462 - DePuy RECLAIM™ Monobloc Revision Femoral Stem
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to convert to a paperless, electronic IFU format, standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	The RECLAIM™ Modular Revision Hip System is a modular, three-component system consisting of a proximal body, a distal stem and a locking bolt assembly. The proximal bodies and distal stems are fitted with mating tapers that permit numerous proximal body/distal stem combinations and

	unlimited rotational positioning of the stem and version of the proximal body. The locking bolt assembly includes a bolt, locking washer and a polymeric retaining clip used to secure the washer to the bolt shank. Proximal bodies and distal stems are offered in a variety of lengths and diameters to accommodate a wide breadth of anatomy. Locking bolt assemblies are supplied in the length corresponding to the proximal body. The DePuy RECLAIM™ Monobloc Revision Femoral Stems are revision femoral implants 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 extramedullary region has standard and high offset options on a polished neck, with a 12/14 AMT trunnion. The devices are intended to be inserted into the femoral canal using the Reclaim Monobloc inserter instruments.
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™ 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.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients.

	At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to convert to a paperless, electronic IFU format, standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the DePuy RECLAIM™ Revision Stems in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	Vision Solution Hip Prosthesis Solution System Hip Prosthesis
Common or usual name	Cemented or Cementless Porous Coated Hip Prosthesis
Classification name	**21 CFR 888.3358**: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3358

Product Code(s)	**LPH**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K953703 - DePuy Vision Solution Hip Prosthesis K030979/K060581 - DePuy Solution System Hip Prosthesis
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	The DePuy Vision Solution Hip Prosthesis are made from ASTM F-75 Cobalt-Chrome-Molybdenum alloy and have a sintered cobalt-chrome molybdenum alloy bead porous coating (Porocoat) applied to the stem. The stems are indicated for cemented or cementless use. The DePuy Solution System Hip Prosthesis, is manufactured from ASTM F-799 Forged Controlled-Carbon Cobalt-Chromium-Molybdenum alloy and has a sintered cobalt-chrome molybdenum alloy bead porous coating (Porocoat) applied to the stem. The porous coating is applied to the

	entire stem with the exception of the tapered stem tip region. The stems are available in 10.5, 12.0 and 13.5mm sizes.
Intended use of the device	The DePuy Solution Hip Prosthesis are indicated for uncemented or cemented use as the femoral components in total hip arthroplasty (THA) for replacing the hip joints of patients whose hip joint has been damaged by inflammatory or non-inflammatory degenerative joint disease, fracture or the failure of a previous 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. The Solution Hip Stem is indicated for cementless use and fixation by biological tissue ingrowth into the porous coating as well as cemented use and fixation in which the porous coating serves as a means to augment the fixation of the prosthesis to the bone cement.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will

	take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the DePuy Solution Hip Prosthesis in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	SUMMIT™ Porocoat Hip Prosthesis SUMMIT™ DuoFix Hip Prosthesis SUMMIT™ Cemented Hip Prosthesis SUMMIT™ FX Cemented Hip Prosthesis SUMMIT™ Basic Press-Fit Hip Prosthesis ACTIS™ Duofix Hip Prosthesis ACTIS™ Duofix Hip Prosthesis Collarless CORAIL™ AMT Hip Prosthesis
Common or usual name	Hip Joint Replacement Prosthesis with porous coating

	Hip Joint Replacement Prosthesis Uncemented Hip Prosthesis
Classification name	**21 CFR 888.3353**: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. **21 CFR 888.3358**: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. **21 CFR 888.3350**: Hip joint metal/polymer semi-constrained cemented prosthesis. **21 CFR 888.3360**: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis. **21 CFR 888.3390**: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3353 Class II – 21 CFR 888.3358 Class II – 21 CFR 888.3350 Class II – 21 CFR 888.3360 Class II – 21 CFR 888.3390
Product Code(s)	**MEH**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented **LPH**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented **JDI**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented **LWJ**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented **KWL**: Prosthesis, Hip, Hemi-, Femoral, Metal **KWY**: Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented

	LZO: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K001991 – DePuy SUMMIT™ Porocoat Hip Prosthesis K011489 – DePuy SUMMIT™ DuoFix Hip Prosthesis K013352 - DePuy SUMMIT™ Cemented Hip Prosthesis K023453 – DePuy SUMMIT™ FX Cemented Hip Prosthesis K030122 – DePuy SUMMIT™ Basic Press-Fit Hip Prosthesis K202472 - DePuy ACTIS™ Duofix Hip Prosthesis K210581 – DePuy ACTIS™ Duofix Collarless Hip Prosthesis K192946 – DePuy CORAIL™ AMT Hip Prosthesis
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to convert to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code

	with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	**SUMMIT Product Family** The DePuy SUMMIT™ Porous Hip is a collarless, titanium, tapered, press-fit femoral stem. The hip stem is manufactured from Titanium (Ti_6Al_4V) and has a sintered commercially pure titanium bead porous coating (Porocoat) applied to the stem. The hip stem consists of 11 body sizes ranging in diameter from 6mm to 18mm with each body size having two offset options. The DePuy SUMMIT™ DuoFix Hip is a non-modular, collarless, Titanium, tapered, press-fit femoral stem. The hip stem is manufactured from ASTM F-620-87 forged Titanium (Ti_6Al_4V) and has a sintered commercially pure Titanium bead porous coating (Porocoat) applied to the stem. The porous coating is applied over the circumferential ridges on the proximal region of the stem. The ridges effectively act as small internal collars and turn shear loading of the bone into compressive loading. The SUMMIT™ Cemented Hip Prosthesis is a flanged, collared, tapered Cobalt-Chromium femoral stem with a smooth surface finish. There are 7 proportional body sizes with two offset options. Distal and proximal PMMA centralizers help assure the stem is centered in the femoral canal. The SUMMIT™ FX Cemented Hip Stem is a flanged, collared, tapered Cobalt-Chromium femoral stem with a smooth surface finish. The SUMMIT™ FX Cemented Hip Stem is offered in 7 sizes with a constant offset. A distal PMMA centralizer helps assure that the stem is centered in the femoral canal. The stem is designed specifically to treat femoral head and neck fractures but can be used for any of the indications listed below.

	The SUMMIT™ Basic Press-Fit Hip Stem is a collared, tapered Titanium femoral stem with a grit blasted finish. The Summit Basic Press-Fit Hip Stem is offered in 7 sizes with a constant neck offset. The stem is intended for cementless, press-fit fixation and is designed specifically to treat femoral head and neck fractures but can be used for any of the indications listed below. **ACTIS Product Family** The DePuy ACTIS™ DuoFix prostheses are manufactured from forged titanium alloy (Ti_6Al_4V) and have a sintered commercially pure titanium bead porous coating (Porocoat) and a thin layer of plasma-sprayed hydroxyapatite (HA) coating. The stem consists of a wide range of stem neck designs and sizes allowing an accurate anatomical match for each patient. The stems are compatible with both unipolar and bipolar heads intended for hemi-arthroplasty and with modular metal and ceramic femoral heads intended for total hip arthroplasty. The ACTIS™ DuoFix Hip Prosthesis – Collarless is prosthesis is manufactured from the exact same materials to that of the collared prosthesis to meet the need of surgeons whose preference is to use a femoral stem without a collar for hip arthroplasty. **CORAIL Product Family** The DePuy CORAIL™ AMT hip stems are manufactured from forged titanium alloy (Ti_6Al_4V) and plasma-sprayed with a hydroxyapatite (HA) coating for bone fixation. The stems consists of a wide range of stem neck designs and sizes allowing an accurate anatomical match for each patient. Corail stems are available with or without a collar, with various neck angles, and with various neck offsets.

Intended use of the device	Total and hemi-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 satisfactory acetabulum and sufficient sound bone to seat and support the components.
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. Hemi hip replacement is indicated in the following conditions: 1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation. 2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation. 3. Avascular necrosis of the femoral head. 4. Non-union of femoral neck fractures. 5. Certain high subcapital and femoral neck fractures in the elderly. 6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement. 7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the DePuy SUMMIT™, DePuy ACTIS™ Duofix, and DePuy CORAIL™ Hip Prosthesis in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19)

	• Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

ACETABULAR PRODUCTS
510k Summaries

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	PINNACLE™ Dual Mobility Liner
Common or usual name	Acetabular Cup Prosthesis
Classification name	**21 CFR 888.3358**: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. **21 CFR 888.3353**: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics

Regulation	Class II – 21 CFR 888.3358 Class II – 21 CFR 888.3353
Product Code(s)	**LPH**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented. **LZO**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented. **MEH**: Prosthesis, Hip, Semi-Constrained, Uncemented, Metal / Polymer, Non-Porous, Calcium Phosphate.
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K200854 – DePuy PINNACLE™ Dual Mobility Liner
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to convert to a paperless, electronic IFU format, standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	The DePuy PINNACLE™ Dual Mobility Liner is manufactured from cobalt-chromium-molybdenum alloy. The Liner is assembled with a taper locking mechanism to PINNACLE™ Acetabular Shells. The inner surface of the Dual Mobility Metal Liner articulates with a BI-MENTUM™ polyethylene

	mobile 54 bearing head. The Dual Mobility construct is compatible with DePuy metal or ceramic modular femoral heads, for use in total hip arthroplasty. The PINNACLE™ Dual Mobility Metal Liner is intended to be used in total hip arthroplasty with a PINNACLE™ Acetabular Cup, a BI-MENTUM™ Dual Mobility Polyethylene Liner, a DePuy femoral stem and a DePuy modular, femoral head.
Intended use of the device	The PINNACLE™ Dual Mobility Metal Liners are designed to provide additional stability where there is an unstable joint and are for use in total hip arthroplasty which 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. The PINNACLE™ Dual Mobility Metal Liners are intended for single use only.
Indications for use	Total hip replacement or hip arthroplasty is indicated in the following conditions: 1. A severely painful and/or disabled joint (typically due to non inflammatory degenerative joint disease). 2. Failed previous hip surgery. 3. Dislocation risks. PINNACLE™ Dual Mobility Metal Liners and Porous-coated PINNACLE™ Acetabular Cups are intended for cementless applications.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels

	and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to convert to a paperless, electronic IFU format, standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the DePuy PINNACLE™ Dual Mobility Liner in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	BI-MENTUM™ ALTRX® Dual Mobility Liners
Common or usual name	Acetabular Component
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	Class II – 21 CFR 888.3353

Product Code(s)	**LZO**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented **MEH**: Prosthesis, Hip, Semi-Constrained, Uncemented, Metal / Polymer, Non-Porous, Calcium Phosphate
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K203532 - BI-MENTUM™ ALTRX® Dual Mobility Liners
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to convert to a paperless, electronic IFU format, standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	The BI-MENTUM™ ALTRX® Dual Mobility Liner is highly cross-linked ultrahigh molecular weight polyethylene (UHMWPE). The liner is mobile (free) in the metallic shell and retained on the prosthetic femoral head.
Intended use of the device	BI-MENTUM™ ALTRX® Dual Mobility Liners are designed to provide additional stability where there is an unstable joint and are for use in total hip arthroplasty that is intended to provide

	increased patient mobility and reduce pain by replacing the damaged hip joint articulation or a previously implanted prosthetic hip joint in patients where there is evidence of sufficient sound bone to seat and support the components. The Bi-Mentum Altrx Dual Mobility Liners are intended for single use only.
Indications for use	BI-MENTUM™ ALTRX® Dual Mobility Liner is indicated for total hip replacement in the following conditions: 1. Osteoarthritis 2. Femoral neck fracture 3. Dislocation risk 4. Osteonecrosis of the femoral head 5. Revision procedures where other treatments or devices have failed are if bone reconstruction so permits
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to convert to a paperless, electronic IFU format, standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.

	Non-clinical testing is provided to support the conditional safety of the BI-MENTUM™ ALTRX® Dual Mobility Liners in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	PINNACLE™ AltrX Acetabular Liners PINNACLE™ 100 with GRIPTION™ Acetabular Cups PINNACLE™ with GRIPTION™ Acetabular Cups PINNACLE™ Acetabular Enhanced Stability Liners
Common or usual name	Polyethylene Acetabular Cup Liner Acetabular Cup with Porous Coating Acetabular Cup Prosthesis
Classification name	**21 CFR 888.3358**: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.

	21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. **21 CFR 888.3350**: Hip joint metal/polymer semi-constrained cemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3358 Class II – 21 CFR 888.3353 Class II – 21 CFR 888.3350
Product Code(s)	**LPH**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented. **LZO**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented. **JDI**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K072963 - DePuy PINNACLE™ AltrX Acetabular Liners K102423 – DePuy PINNACLE™ AltrX Acetabular Liners K132959 - DePuy PINNACLE™ AltrX Acetabular Liners K090998 - DePuy PINNACLE™ 100 with GRIPTION™ Acetabular Cups K093646 - DePuy PINNACLE™ with GRIPTION™ Acetabular Cups K033273 – DePuy PINNACLE™ Acetabular Enhanced Stability Liners K001534 – DePuy PINNACLE™ Acetabular System
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and

	is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	**PINNACLE™ AltrX** The DePuy PINNACLE™ AltrX Acetabular Liner is part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The liner is manufactured from ultra-high molecular weight polyethylene (UHMWPE), which locks into a porous coated, hemispherical outer shell component manufactured from titanium alloy (Ti_6Al_4V). The liner component articulates with a metal or ceramic femoral head of an appropriate diameter. The PINNACLE™ AltrX Liners are cross-linked UHMWPE acetabular cup liners that are available in a neutral, lateralized neutral, lipped or lateralized face-changing orientation. The subject liners are intended for use with modular, unipolar, self-centering (bipolar), M-Spec or ceramic femoral heads within the 28mm-48mm size range.

	PINNACLE™ with GRIPTION™ The PINNACLE™ Acetabular System is part of a modular system for use in total hip replacement. The acetabular component is provided as two separate units, a porous coated hemispherical outer shell manufactured from titanium alloy (Ti_6Al_4V) and a liner manufactured from ultra high molecular weight polyethylene (UHMWPE) or high-carbon cobalt chrome (CrCoMo), both of which lock into the outer shell. The liner component articulates with a femoral head of an appropriate diameter. The subject acetabular cup is coated with a proprietary titanium porous coating, GRIPTION™. **PINNACLE™ Enhanced Stability Liner** The PINNACLE™ Enhanced Stability (ESL) Marathon™ liners are cross-linked UHMWPE acetabular cup liners that are available in a lateralized neutral, or lateralized face-changing orientation. The liners have inner diameters (ID) intended for use with modular, unipolar, or self-centering (bipolar) femoral heads within the 28mm-48mm size range. The outer diameters (OD) are geometrically the same as other Pinnacle Acetabular Cup Liners, in a 44mm-76mm size range offering. There is an addition of a Charnley-style bore on sizes 36mm-48mm ID to increase stability. **PINNACLE™ Acetabular System** The DePuy PINNACLE™ Acetabular System is part of a modular system for use in total hip replacement. The acetabular component is provided as two separate units, a porous coated hemispherical outer shell manufactured from titanium alloy (Ti_6Al_4V) and a liner manufactured from ultra-high molecular weight polyethylene (UHMWPE), which looks into the outer shell. The liner component articulates with a femoral head of an appropriate diameter.

Intended use of the device	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. **PINNACLE™ AltrX** The DePuy PINNACLE™ AltrX Acetabular Liner is intended to be used with DePuy PINNACLE™ metal acetabular shells, and DePuy metal or ceramic femoral heads to resurface the acetabular socket in cementless total hip arthroplasty. **PINNACLE™ with GRIPTION™** The DePuy PINNACLE™ GRIPTION™ porous-coated Acetabular Cup total hip components are indicated for cementless use with fixation provided by biological tissue ingrowth into the porous coating. **PINNACLE™ Enhanced Stability Liner** The ESL Marathon™ Polyethylene Liners are intended to be used with the DePuy PINNACLE™ metal acetabular shells, modular femoral heads, unipolar femoral heads, and self-centering heads to resurface the acetabular socket in cementless total hip arthroplasty. **PINNACLE™ Acetabular System** All Pinnacle porous-coated acetabular shells are indicated for cementless application.
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.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the DePuy PINNACLE™ Acetabular System, DePuy PINNACLE™ Altrx, PINNACLE™ with GRIPTION™ and PINNACLE™ Enhanced Stability Acetabular Cups and Liners in the MR environment, including assessment of;

	• Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	PINNACLE™ Revision System PINNACLE™ Duofix HA Acetabular Cup Prosthesis DURALOC™ Option Acetabular Cup System DURALOC™ 100C Acetabular Cup DURALOC™ Cementless Acetabular Cup System MARATHON™Cross-linked Polyethylene Acetabular Cup Liners 36mm MARATHON™ Polyethylene Liners Profile Hip Acetabulum Prosthesis EMPHASYS™ Acetabular System

Common or usual name	Acetabular Cup Prosthesis Cementless Acetabular Cup Prosthesis
Classification name	**21 CFR 888.3358**: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. **21 CFR 888.3353**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented. **21 CFR 888.3350**: Hip joint metal/polymer semi-constrained cemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3358 Class II – 21 CFR 888.3353 Class II – 21 CFR 888.3350
Product Code(s)	**LPH**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented. **LZO**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented. **JDI**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K033338 – DePuy PINNACLE™ Revision System K192919 – DePuy PINNACLE™ Duofix HA Acetabular Cup Prosthesis K040544 – DePuy DURALOC™ Option Acetabular Cup System K951674 - DePuy DURALOC™ 100C Acetabular Cup K961186 - DePuy DURALOC™ Cementless Acetabular Cup System K994415 – DePuy MARATHON™Cross-linked Polyethylene Acetabular Cup Liners K010171 - DePuy 36mm MARATHON™ Polyethylene Liners

	K863184 - DePuy Profile Hip Acetabulum Prosthesis K221636 – DePuy EMPHASYS™ Acetabular System
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	**PINNACLE™ Revision System** The PINNACLE™ Revision System is a modular system for resurfacing the acetabulum in total hip arthroplasty. The system consists of two separate units, a shell and a liner. The shell substrate is manufactured from forged or wrought titanium alloy (Ti_6Al_4V). The outer porous coating (Porocoat) consists of commercially pure titanium beads metallurgically bonded to the shell substrate. The interior of the shell is designed to mate with a variety of styles of liners that lock into the shell. The liner is manufactured from Ultra-high molecular weight polyethylene (UHMWPE). The liners contain multiple ARDs (anti-rotation devices) that engage mating shell features to prevent rotation within the shell. The ARDs enable variable rotational alignment of Face Changing (+4/10) and lipped liners for patient appropriate positioning. The acetabular liner articulates with a compatible femoral head of appropriate diameter.

	PINNACLE™ Duofix HA The PINNACLE™ Duofix HA Acetabular Cup Prosthesis is a sintered, porous-coated (Porocoat®) hemispherical outer acetabular shell manufactured from titanium alloy (Ti-6Al-4V) with a thin layer of hydroxyapatite (HA) coating applied. The interior of the acetabular cup is designed with a groove and a taper for use with either an ultra-high molecular weight polyethylene (UHMWPE) or metal acetabular cup liner, which lock into the shell. Articulation occurs between the liner, and a femoral head with the appropriately sized diameter. The shells contain an apical threaded hole to allow the surgeon to attach the shell insertion instrument and grasp the shell during implantation. An optional titanium alloy (Ti-6Al-4V) apical hole plug is available to screw into the threaded apical hole of the shell. The plug is intended to occlude the apical hole in order to prevent particulate migration and provide polyethylene support. The PINNACLE™ Duofix HA Acetabular Cup Prosthesis is provided in shell diameter sizes 48mm through 66mm in both the "No Hole" (100 series) and the "Cluster Hole" (Sector series) configurations. **DURALOC™ Option** The DURALOC™ Option Acetabular Cup System consists of a UHMWPE acetabular cup liner secured to a porous-coated Ti-6Al-4V acetabular shell. The acetabular system articulates with previously cleared 22.225mm or 28mm femoral heads. The acetabular cups are sized from 44mm to 66mm, in 2 mm increments. The liners are available in two styles: neutral and lipped. Liners with a 22.225mm inner diameter are offered in outer

	diameters of 44mm and 46mm. Liners with a 28mm inner diameter are offered in outer diameters of 48/50mm, 52mm, 54/56mm, 58/60mm, and 62/64/66mm. The liner interlock allows the liner to be rotated to match the patient's anatomy. A locking ring, manufactured from Co-Cr-W-Ni alloy, is used to secure the liner. **DURALOC™ 100C Cup** The DePuy DURALOC™ 100C is a porous coated Co-Cr-Mo alloy acetabular cup which is available in 10 sizes, ranging from 48mm to 66mm in outer diameter. The porous coated outer surface is intended to achieve biological fization through tissue ingrowth, or to enhance the strength of the bone cement/prosthesis interface if the cup is used with bone cement. The DePuy DURALOC™ 100C also features a polished inner surface. This surface is in full congruent contact with the polyethylene liner, assuring full dome loading of the polyethylene. **DURALOC™ Cementless Acetabular Cup** The DePuy DURALOC™ Cementless Acetabular Cups are all porous coated Ti_6Al_4V alloy acetabular cup metal shells and will be available in various sizes with outer diameters ranging from 38mm to 80mm. All of the cups have screw holes, either dome or peripheral, for adjunctive fixation. All of the DePuy DURALOC™ Acetabular Cups are intended to be used with DePuy DURALOC™ polyethylene liners and locking rings to resurface the acetabular socket in cemented or cementless total hip replacement. **DePuy MARATHON™Cross-linked Polyethylene Acetabular Cup Liners** The DePuy MARATHON™Cross-linked Polyethylene Acetabular Cup Liners are UHMWPE acetabular cup liners that are available with 28mm or 32mm inner diameters and with a neutral or 10° lip. The 28mm liners are available in sizes to fit DURALOC™ metal acetabular shells with outer diameters of 48-74mm. The 32mm liners are available in sizes to fit DURALOC™ metal acetabular shells with

	outer diameters of 52-80mm. The polyethylene liners are locked into the DURALOC™ metal shells with a metal wire locking ring which is supplied with the metal shells. The DePuy MARATHON™Cross-linked Polyethylene Acetabular Cup Liners are manufactured from UHMWPE that has been cross-linked by exposure to radiation in a very low oxygen environment and then heat treated prior to machining of the liners. The cross-linked polyethylene has physical and mechanical properties that are similar to those of standard UHMWPE but has increased resistance to oxidation and wear. Marathon cross-linked UHMWPE meets all of the specifications of ASTM F648. The DePuy MARATHON™36mm liners are UHMWPe acetabular cup liners that are available with a 36mm inner diameter and are lateralized 4mm. They are available in a neutral orientation and with a 10degree lip. They are geometrically identical to other DURALOC™ Acetabular Cup Liners with the exception of having a larger (36mm) inner diameter intended for use with 36mm femoral heads. **DePuy Profile Hip Acetabulum Prosthesis** The DePuy Profile Hip Acetabulum Prosthesis manufactured from ASTM-F-136 Titanium-Aluminium-Vanadium alloy (Ti_6Al_4V). The porous coating is manufactured from ASTM-F-67 Commercially Pure (CP) Titanium. The prosthesis articulates with the Profile Hip Femoral Prosthesis. The Profile Hip Acetabulum prosthesis can also be utilized with other femoral prostheses having a head size that matches the inner diameter of the Profile Hip Acetabular prosthesis. **EMPHASYS™ Acetabular System** The EMPHASYS™ Acetabular System includes porous-coated acetabular shells in three configurations (No-Hole, 3-Hole and Multi-Hole) and AOX polyethylene liners in three configurations (Neutral, +4 Neutral and ELV).

Intended use of the device	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. **PINNACLE™ Revision Acetabular System** The PINNACLE™ Revision Acetabular System is intended to be used to resurface the acetabular socket in cemented or cementless total hip arthroplasty. **PINNACLE™ Duofix HA** The PINNACLE™ Duofix HA Acetabular Cup Prosthesis is indicated for cementless application. **DURALOC™ Option** The DURALOC™ Option Acetabular Cup System is indicated for cementless application. **DURALOC™ 100C Cup** The DePuy DURALOC™ 100C Cup is intended to be used with the DURALOC™ polyethylene liners to resurface the acetabular socket in cemented or cementless total hip replacement. **DURALOC™ Cementless Acetabular Cup** The DePuy DURALOC™ Cementless Acetabular Cups are intended to be used with DURALOC™ polyethylene liners to resurface the acetabular socket in cemented or cementless total hip replacement. **DePuy MARATHON™Cross-linked Polyethylene Acetabular Cup Liners** The DePuy MARATHON™Cross-linked Polyethylene Acetabular Cup Liners are intended to be used with the DePuy DURALOC™ metal acetabular shells to resurface the acetabular socket in cemented or cementless total hip replacement. **DePuy Profile Hip Acetabulum Prosthesis** The DePuy Profile Hip Acetabulum Prosthesis is designed to be implanted with bone cement.

	EMPHASYS™ Acetabular Cups The system is intended for use with a compatible DePuy femoral stem and modular head as a total hip prosthesis. EMPHASYS™ Acetabular Cups are indicated for cementless use only.
Indications for use	Total hip arthroplasty is indicated for total hip replacement 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.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.

	Non-clinical testing is provided to support the conditional safety of the PINNACLE™ Revision System, PINNACLE™ Duofix HA, DURALOC™ Option Acetabular Cup System, DURALOC™ 100C Cup, DURALOC™ Cementless Acetabular Cup, MARATHON™Cross-linked Polyethylene Acetabular Cup Liners, Profile Hip Acetabulum Prosthesis and EMPHASYS™ Acetabular System in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

FEMORAL HEADS
510k Summaries

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	Delta Ceramic Femoral Heads Delta TS Ceramic Femoral Heads Elite Femoral Head
Common or usual name	Ceramic Femoral Ball Prosthesis Temporary Hip Joint Replacement Prosthesis
Classification name	**21 CFR 888.3353** - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. **21 CFR 888.3350**: Hip joint metal/polymer semi-constrained cemented prosthesis.
Class	II

Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3353 Class II – 21 CFR 888.3350
Product Code(s)	**LZO -** Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented. **JDI**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented.
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K011533, K031803, K062748 - DePuy Delta Ceramic Femoral Heads K071830 - DePuy Delta TS Ceramic Femoral Heads K871867 - DePuy Elite Femoral Heads
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions.

	There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	**Delta Femoral Heads** The DePuy Delta Ceramic Femoral Heads are ceramic femoral ball prostheses, comprised of an alumina composite material, intended for use with DePuy femoral hip stems with a corresponding taper design. The ceramic femoral heads mechanically lock with a femoral hip stem via a taper junction and articulate with a polyethylene acetabular component. The DePuy Delta TS (Taper Sleeve) Ceramic Femoral Heads are designed for use as the femoral head component in total hip arthroplasty procedures. The femoral head is manufactured from an alumina composite ceramic material and includes an internal titanium alloy sleeve to mate with DePuy femoral hip stems with a corresponding taper. The ceramic femoral head mechanically locks with the femoral hip stem via a taper junction and articulates with a polyethylene acetabular component. The DePuy Delta TS Ceramic Femoral Heads are available in femoral head outer diameters of 28mm, 32mm, 36mm, 40mm and 44mm. The internal bore of the titanium sleeve is available in a 12/14 option. **Elite Femoral Heads** The DePuy Elite Femoral Heads are sterile, single use, high nitrogen stainless steel implants intended for use with modular femoral stems in Hemi-Hip Arthroplasty (HHA) or Total Hip Arthroplasty (THA).

Intended use of the device	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	DePuy Femoral Heads are indicated for use as the femoral head component in total hip arthroplasty procedures. 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.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new

	Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the DePuy Delta and Elite Femoral Heads in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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	13th December 2023
Name of device	
Trade or proprietary name	Self-Centering Hip
Common or usual name	Total or Hemi-Hip Arthroplasty Prosthesis
Classification name	**21 CFR 888.3390**: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3390
Product Code(s)	**KWY:** Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented.

Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K812672 - DePuy Self-Centering Hip
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to convert to a paperless, electronic IFU format, standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	The DePuy Self-Centering Hip device is a femoral, hemi-hip (metal/polymer) prosthesis designed to replace the femoral head and consists of 2 major parts: a metallic alloy outer shell, and a 2 piece Ultra High Molecular Weight Polyethylene (UHMWP) bearing insert and metal retaining ring, assembled for use in conjunction with any metallic alloy total hip femoral component with a 22mm or 32mm diameter head.
Intended use of the device	SELF-CENTERING Hip Prostheses are intended to be used for hemi-hip arthroplasty where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral stem.

Indications for use	Self-Centering hip arthroplasty is indicated in the following conditions: 1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation. 2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation. 3. Avascular necrosis of the femoral head. 4. Non-union of femoral neck fractures. 5. Certain high subcapital and femoral neck fractures in the elderly. 6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement. 7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to convert to a paperless, electronic IFU format, standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.

	Non-clinical testing is provided to support the conditional safety of the DePuy Self-Centering Hip in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	HPS Femoral Ball Head Total Hip Ball Femoral Head Articul/eze Femoral Heads Modular M Head 36mm Femoral Heads Articul/eze Ceramic Heads
Common or usual name	Femoral Prosthesis Temporary Hip Joint Replacement Prosthesis Femoral Heads

	Ceramic femoral ball prosthesis
Classification name	**21 CFR 888.3350**: Hip joint metal/polymer semi-constrained cemented prosthesis. **21 CFR 888.3358**: Hip joint metal/polymer/metal, semi-constrained, porous-coated, uncemented prosthesis. **21 CFR 888.3353 -** Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3350 Class II – 21 CFR 888.3358 Class II – 21 CFR 888.3353
Product Code(s)	**JDI**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented. **LPH**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented. **LZO**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented.
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K860701 - DePuy HPS Femoral Ball Heads K880269 - DePuy Total Hip Ball Femoral Heads K883460 - DePuy Articul/eze Femoral Heads K060031 - DePuy Modular M Heads K980513/K120599 - DePuy 36mm Femoral Heads K222296 - Articul/eze Ceramic Heads
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners,

	Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	**HSP and Total Hip Femoral Heads** The DePuy HSP and Total Hip Femoral Ball Heads are made from ASTM F-75 Cobalt Chromium Molybdenum. Femoral ball heads with corresponding internal tapers are available to allow for interchangeability. The different femoral ball heads provide three different neck length and two head sizes. **Articul/eze Femoral Heads** The DePuy Articul/eze Femoral Heads are sterile, single use, metal implants intended for use with modular femoral stems in Hemi-Hip Arthroplasty (HHA) or Total Hip Arthroplasty (THA). The products are intended for use in both Primary and Revision Hip Arthroplasty. The modular femoral heads are intended to replace the native femoral head and are mechanically fixed to the modular femoral stems by means of a taper trunnion. The Modular Femoral Head and Modular Femoral Stem components are assembled intraoperatively and articulate against an appropriate acetabular component.

	Modular M Heads The DePuy Modular M Heads are manufactured from wrought Co-Cr-Mo alloy and are available in: • 40, 44, and 48 mm diameters with a 12/14 Articul/eze taper and –2, +1.5, +5, +8.5, +12 and +15.5 mm neck lengths. All of the Articul/eze taper femoral heads have an internal taper that mate with a corresponding external taper on compatible cemented or cementless femoral stems. 40 and 44 mm diameters with an 11/13 S-ROM taper and -3, +0, +3, +6, +9 and +12 mm neck lengths. The 48 mm heads with the 11/13 taper are available in +0, +3, +6, +9 and +12 mm neck lengths. All of the S-ROM taper femoral heads have an internal taper that mate with a corresponding external taper on compatible cemented or cementless femoral stems. **36mm Femoral Heads** The DePuy 36mm Femoral Heads are Co-Cr-Mo alloy femoral heads available in various taper sizes and offsets which are designed to mate with femoral hip stems which have matching neck taper sizes. The offset vary to allow the surgeon flexibility in lateralization of the hip joint. **ARTICUL/EZE Ceramic Heads** 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 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	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.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the DePuy HPS, Total Hip Femoral Ball Heads, DePuy Articul/eze, Modular M, 36mm Femoral Heads and ARTICUL/EZE Ceramic Heads in the MR environment, including assessment of;

	• Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	S-ROM Femoral Head
Common or usual name	Temporary Hip Joint Replacement Prosthesis
Classification name	**21 CFR 888.3350**: Hip joint metal/polymer semi-constrained cemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3350
Product Code(s)	**JDI:** Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented.

Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K851422/K920317 – S-ROM Femoral Heads
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	The S-ROM Femoral Heads, are a nitrogen ion implanted modular femoral head. They are composed of wrought cobalt chrome alloy conforming to ASTM F799. The outer bearing surface is spherical, finished to a high polish and implanted with Nitrogen Ions. The bore of the S-ROM LF Femoral Head is machined to a precise taper angle to mater with compatible S-ROM Femoral Stems. The S-ROM Femoral Heads are offered in a variety of sizes.
Intended use of the device	**INTENDED USE – TOTAL HIP PROSTHESIS** 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.

	INTENDED USE - HEMI-HIP PROSTHESIS Hemi-Hip Prostheses are intended to be used for hemi-hip arthroplasty where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral stem.
Indications for use	**INDICATIONS – TOTAL HIP PROSTHESIS** 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. Certain cases of ankylosis. **INDICATIONS – HEMI-HIP PROSTHESIS** Hemi-hip arthroplasty is indicated in the following conditions: 1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation. 2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation. 3. Avascular necrosis of the femoral head. 4. Non-union of femoral neck fractures. 5. Certain high subcapital and femoral neck fractures in the elderly. 6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement. 7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the S-ROM Femoral Heads in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

COMPONENTS
510k Summaries

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	5.0mm Tapered Head Peripheral Screw Low Profile Bone Screw Acetabular System Screws Griptionn TF 5.5mm Locking Screws
Common or usual name	Acetabular Screw Bone Screw Acetabular Cup and Liner Locking Screws
Classification name	**21 CFR 888.3350**: Hip joint metal/polymer semi-constrained cemented prosthesis.

	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener. **21 CFR 888.3358** - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. **21 CFR 888.3353** - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3050 Class II – 21 CFR 888.3040 Class II – 21 CFR 888.3358 Class II – 21 CFR 888.3353
Product Code(s)	**JDI**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented. **HWC**: Screw, Fixation, Bone. **LPH**: Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented. **LZO**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented.
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K861979 - 5.0mm Tapered Head Peripheral Screw K970929 - DePuy Low Profile Bone Screw K983014 - Acetabular System Screws K123924 - Griptionn TF 5.5mm Locking Screws
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and

	is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	**DePuy 5.0mm Tapered Head Peripheral Screw** The DePuy 5.0mm Tapered Head Peripheral Screw provides a peripheral fixation in the DePuy Solution Cup System. It comes in 8 lengths in 5mm increments (25-60mm) with a 5.0mm diameter thread. The use of orthopedic screws provides the orthopedic surgeon a means of ancillary bone fixation in reconstructive surgeries. These implants are intended to provide additional stability to implanted orthopedic devices and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. **DePuy Low Profile Bone Screw** The DePuy Low Profile Bone Screw, manufactured in both Ti_6Al_4V and Co-Cr-Mo alloys, are available in twelve lengths (15-10mm) with a 6.5mm major diameter. The head of the screw is

	designed with a “low profile” to allow the head to be placed below the surface of the component being fixed. An internal hex fitting in the head is used for instrument (a hex drive) insertion of the screw during surgery. The distal two-thirds of the screw is coarsely threaded while the proximal one-third is smooth with a polished stain finish. The screw has a distal flute to aid in insertion into cancellous bone. **PINNACLE™ Cancellous Bone Screws and P.F.C Sigma Porocoat Tray Screws** The DePuy PINNACLE™ Cancellous Bone Screws and P.F.C Sigma Porocoat Tray Screws are to be used with the Acetabular System. They are manufactured from titanium alloy (Ti-Al6-V4). **DePuy Gription TF 5.5mm Locking Screws** The DePuy Gription TF 5.5mm locking screws are used for mechanical fixation with the DePuy Gription TF Acetabular System, which consists of a variety of augments, buttresses and shims. The lengths include 14-24mm in increments of 2mm and lengths 25-70mm in increments of 5mm.
Intended use of the device	The DePuy Bone Screws are indicated for use in primary or revision hip surgery, namely for peripheral screw fixation for acetabular cups.
Indications for use	The DePuy Bone Screws are indicated for use in primary or revision hip surgery, namely for peripheral screw fixation for acetabular cups. DePuy Bone Screws are indicated for use as an ancillary fixation device to be used with tibial and acetabular components in total knee and hip arthroplasty.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels

	and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the DePuy Bone Screws in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	GRIPTION™ TF Acetabular Augment System
Common or usual name	Acetabular Augments, Buttresses, Shims
Classification name	**21 CFR 888.3350**: Hip joint metal/polymer semi-constrained cemented prosthesis. **21 CFR 888.3358**: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. **21 CFR 888.3353**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented
Class	III/II

Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3350 Class II – 21 CFR 888.3358 Class II – 21 CFR 888.3353
Product Code(s)	**JDI**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented **LPH**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented. **LZO**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented.
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K100391 - DePuy GRIPTION™ TF Acetabular Augment System
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and

	can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. The scope of this submission incorporates the Hip Acetabular Augments, Buttresses and Shim components solely, no Knee implant product codes are included.
Device description	**GRIPTION™ TF Acetabular Augments** The DePuy GRIPTION™ TF Acetabular Augment System provides an alternative to structural allograft for augmenting moderate to large-sized segmental acetabular defects encountered in acetabular reconstruction. The GRIPTION™ TF Acetabular Augment implants are manufactured from Commercially Pure (CP) Titanium powder conforming to ASTM Specification F-1580. The Acetabular Augment implants are used to fill an acetabular defect giving the acetabular shell support where bone is missing or inadequate. The Augment has an inside diameter designed to mate with the outside diameter of the Pinnacle Acetabular Shell system. The porous GRIPTION™ TF acetabular augment is affixed to the mating acetabular cup using bone cement or mechanical fixation. The Acetabular Augments incorporate screw holes that allow for the use of bone screws for adjunct fixation of the acetabular component to the native bone. The Acetabular Augments also incorporate a slot feature used to mechanically attach the augment to the acetabular shell with or without the use of bone cement. The assembled porous titanium augment/acetabular construct is intended for cemented or cementless use. **GRIPTION™ TF Acetabular Buttresses** The GRIPTION™ TF Acetabular Buttress implants are manufactured from Commercially Pure (CP) Titanium powder conforming to ASTM Specification F-1580. The Acetabular Buttress implants are

	used to span an acetabular defect, giving the acetabular shell support where bone is missing or inadequate. The Buttress implants have a spherical diameter matching those of DePuy Orthopaedics' current acetabular shell sizing. The porous GRIPTION™ TF Acetabular Buttress is affixed to the mating acetabular cup using bone cement. The assembled porous titanium buttress/acetabular construct is intended for cemented or cementless use. The Acetabular Buttress implants also incorporate screw holes that allow for the use of bone screws for adjunct fixation of the acetabular component to the native bone. **GRIPTION™ TF Shims** The GRIPTION™ TF Acetabular Shim implants are manufactured from Commercially Pure (CP) Titanium powder conforming to ASTM Specification F-1580. The Acetabular Shim implants are used to mate with the Buttress implants to raise or support the end of the Buttress when pelvic geometries are not flat. The Shim implant has clearance holes for the Buttress screw adjunct fixation. The porous GRIPTION™ TF Shim is affixed to the mating Buttress using bone cement. The assembled porous titanium buttress/shim construct is intended for cemented or cementless use.
Intended use of the device	The DePuy GRIPTION™ TF Acetabular Augment System is intended to provide the orthopaedic surgeon with a prosthetic alternative to structural allograft in cases of segmental acetabular deficiencies.
Indications for use	The DePuy GRIPTION™ TF Acetabular Augments, Buttresses and Shims are indicated for use with the Pinnacle Acetabular Cup System, the Pinnacle Bantam Acetabular Cup System and the Pinnacle Revision Acetabular Cup System for total hip replacement in the following conditions: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoir 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. The porous GRIPTION™ TF titanium acetabular augment is affixed to the mating acetabular cup using bone cement or mechanical screw fixation. The assembled porous titanium augment is intended for cemented or cementless use. The porous GRIPTION™ TF titanium shim is affixed to the mating buttress using bone cement. This porous GRIPTION™ TF titanium buttress is affixed to the mating acetabular cup using bone cement. The assembled buttress/acetabular cup construct is intended for cemented or cementless use.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code

	with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the DePuy GRIPTION™ TF Acetabular Augment System in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December2023
Name of device	
Trade or proprietary name	Cement Restrictor
Common or usual name	Cement Restrictor
Classification name	**21 CFR 888.3350**: Hip joint metal/polymer semi-constrained cemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3050
Product Code(s)	**JDI**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented.

Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K800894 - DePuy Cement Restrictor
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to convert to a paperless, electronic IFU format, standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	The DePuy Cement Restrictor is designed for placement in the prepared medullary canal to restrict bone cement migration into the distal medullary canal on implantation of a femoral hip prosthesis. This device is an ultra high molecular weight polyethylene cylinder with a threaded

	hole for attachment to the Insertion Instrument and having multiple rows of flexible segmented fins to provide a mechanical fixation in the medullary canal.
Intended use of the device	The DePuy Cement Restrictor is indicated for use in cementing total hip or endoprosthetic femoral components.
Indications for use	The UHMWPe cement restrictor is intended for use in cemented total and hemiarthroplasty procedures to restrict distal flow of bone cement in the femoral medullary cavity.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.

	Non-clinical testing is provided to support the conditional safety of the DePuy Cement Restrictors in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	Modified Profile Hip PMMA Cement Spacer
Common or usual name	Cement Spacer
Classification name	**21 CFR 888.3350**: Hip joint metal/polymer semi-constrained cemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3050
Product Code(s)	**JDI**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented.

Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K871510 - Modified Profile Hip PMMA Cement Spacer
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	Cementralizers® and cement spacers are polymethylmethacrylate (PMMA) spacers intended for use in cemented total hip arthroplasty to provide a uniform thickness of bone cement between the femoral component and the surrounding bone. The device is machined from crosslinked polymethylmethacrylate copolymer and its function is to position the distal stem of the Modified Profile Hip Femoral Prosthesis within the medullary canal of the proximal femur. The spacer

	provides for a more uniform cement mantle by maintaining alignment of the femoral stem within the medullary canal. The PMMA space itself repolymerizes with the surrounding bone cement to become an integral part of the cement mantle.
Intended use of the device	The Modified Profile Hip PMMA Spacer is intended for use with the Modified Profile Hip when it is implanted as a cemented prosthesis in cemented hip replacement.
Indications for use	The Modified Profile Hip PMMA Spacer is indicated for use in cemented hip replacement.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.

	Non-clinical testing is provided to support the conditional safety of the Modified Profile Hip PMMA Spacer in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	Apex Hole Eliminator PS
Common or usual name	Acetabular Cup Apical Hole Plug
Classification name	**21 CFR 888.3358** - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3358
Product Code(s)	**LPH**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented.

Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K963309 – Apex Hole Eliminator PS
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	The Apex Hole Eliminator is a plug with machined threads having standard tolerances. The device locks into the acetabular cup by means of a taper on the trailing edge of the component. This taper is designed to seat on the leading edge of the apical hole of the cup, preventing the hole plug from being screwed through the apical hole. When seated, the front or inside surface of the Apex Hole Eliminator PS sits flush with the concave inner surface of the metal shell of the

	acetabular cup thereby avoiding deformation or wear of the UHMWPe liner against the edges of the hole plug.
Intended use of the device	The Apex Hole Eliminator PS is a threaded plug intended to close the apical hole of the Duraloc series two-piece acetabular cups. It is intended for use in Duraloc cups implanted with or without bone cement. It can be used after insertion of the acetabular cup in a cementless technique once the cup is well seated to prevent movement of blood or particles from behind the shell through the hole or it can be placed prior to insertion of the cup if the cup is being cemented into place to prevent cement from coming through the apical hole. The Apex Hole Eliminator PS also provides support of the polyethylene liner utilized in the metal shell, assuring full, congruent, uninterrupted support of the liner within the shell and eliminating the potential of cold flow of the liner into the apical hole of the metal shell.
Indications for use	The Apex Hole Eliminator PS is a threaded plug intended to close the apical hole of the Duraloc series two-piece (metal shell and UHMWPe liner) acetabular cups. It is intended for use in Duraloc cups implanted with or without bone cement.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries.

	Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the Apex Hole Eliminator PS in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	J-Fx Cerclage System
Common or usual name	Cerclage Fixation Device
Classification name	**21 CFR 888.3030**: Single/multiple component metallic bone fixation appliances and accessories.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3030
Product Code(s)	**LRN**: Wire, Surgical

Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K971682 - J-Fx Cerclage System
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	The J-Fx Cerclage System consists of an implantable cable and crimp sleeve for use as an internal cerclage fixation system in the management of fractures and reconstructive surgery. The cobalt chromium multifilament cable can be used with the cobalt chromium crimp sleeve. The crimp

	sleeve is secured to the tensioned cable using a specially designed crimping instrument. The cable and sleeve are available either in stainless steel or cobalt-chromium alloy.
Intended use of the device	The J-Fx Cerclage System is indicated for use as a cerclage fixation device in general orthopedic repairs. These include procedures such as: reinforcement of bone; reattachment of the greater trochanter; fixation of long bone fractures with grafting; and fixation of patellar fractures.
Indications for use	The J-Fx Cerclage System is indicated for use as a cerclage fixation device in general orthopedic repairs. These include procedures such as: reinforcement of bone; reattachment of the greater trochanter; fixation of long bone fractures with grafting; and fixation of patellar fractures.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions.

	There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the J-Fx Cerclage System in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

510(K) SUMMARY

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	13th December 2023
Name of device	
Trade or proprietary name	S-ROM™ Hip System Locking Plug S-ROM™ Screws
Common or usual name	Locking Plug
Classification name	**21 CFR 888.3350**: Hip joint metal/polymer semi-constrained cemented prosthesis. **21 CFR 888.3358** - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics

Regulation	Class II – 21 CFR 888.3350 Class II – 21 CFR 888.3358
Product Code(s)	**JDI**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented. **LPH**: Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented.
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate – K102080 – RECLAIM™ Revision Hip System** K963206 - S-ROM™ Hip System Locking Plug K951000 - S-ROM™ Screws
Reason for 510(k) submission	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	**S-ROM™ Hip System Locking Plug** The Locking Plug consists of a head and body. The head has both internal threading and external sections (barbs). The internal threading allows attachment of the insertion tool to the Locking Plug. The body is cylindrical with an external lip. Both the external serrations of the head and the

	lip of the Locking Plug body aid in resisting disengagement of the Locking Plug from the shell/liner assembly. The Locking Plug is available in both 3.5mm and 5.0mm sizes. **S-ROM™ Screws** The S-ROM™ Screws are available in a choice of sizes and are made of anodized titanium alloy (Ti-Al6-V4/TiO2) and ultrahigh molecular weight polyethylene (UHMWPE). The use of orthopedic screws provides the orthopedic surgeon a means of ancillary bone fixation in reconstructive surgeries. These implants are intended to provide additional stability to implanted orthopedic devices and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing.
Intended use of the device	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	Total hip arthroplasty is indicated for total hip replacement 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.
Substantial Equivalence	DePuy Ireland UC has compiled a Bundled 510(k) Premarket Notification to expand the labeling for the DePuy Hip Portfolio of Implants, which includes Hip Stems, Acetabular Shells and Liners, Femoral Heads, and Hip Components, to provide updated information regarding the MRI compatibility of its devices. A program of MRI Safety Evaluation testing has been carried out and

	is reported within the 510(k), and appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the S-ROM™ Hip System Locking Pin and S-ROM™ Screws in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.