July 11, 2024

DePuy Ireland UC
Meagan Robles
Regulatory Affairs Project Leader
Loughbeg
Ringaskiddy, Co. Cork Munster
Ireland

Re: K241000
Trade/Device Name: ATTUNE™ Revision Knee System; DePuy Knee Prosthesis System Universal Stem Extensions and Universal Femoral Metaphyseal Sleeves; DePuy Sigma PS Femoral Components; DePuy Sigma Cruciate Retaining (C/R) Porocoat Femoral Components; S-ROM™ NOILES™ Rotating Hinge Knee System; DePuy P.F.C. ™ SIGMA™ Total Knee Prosthesis; DePuy SIGMA™ Total Knee Prosthesis;
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH
Dated: April 11, 2024
Received: April 12, 2024

Dear Meagan Robles:

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,

Lixin Liu -S

Lixin Liu, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241000

Device Name
ATTUNE Revision Knee System; DePuy Knee Prosthesis System Universal Stem Extensions and Universal Femoral Metaphyseal Sleeves; DePuy Sigma PS Femoral Components; DePuy Sigma Cruciate Retaining (C/R) Porocoat Femoral Components; S-ROM NOILES Rotating Hinge Knee System;DePuy P.F.C. SIGMA Total Knee Prosthesis;DePuy SIGMA™ Total Knee Prosthesis

Indications for Use *(Describe)*

ATTUNE™ Revision Knee System

Candidates for total knee replacement include patients with

• A severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, or rheumatoid arthritis
• Moderate valgus, varus, or flexion deformities
• Avascular necrosis of the femoral condyle
• A previous unsuccessful knee replacement, osteotomy, or other knee procedure

ATTUNE Revision Knee System implants are designed for use in total knee arthroplasty for patients with:

• Absence or loss of both cruciate ligaments
• Moderate varus-valgus or flexion instability that requires a bearing surface with increased constraint in the clinical judgment of the surgeon
• Bone loss that requires supplemental fixation in the clinical judgment of the surgeon

The porous-coated metaphyseal sleeves are intended for either cemented or cementless applications.

ANY NON POROUS-COATED COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY.

DePuy Knee Prosthesis System Universal Stem Extensions and Universal Femoral Metaphyseal Sleeves

The DePuy Universal Femoral Metaphyseal Sleeve and Universal Stem components are intended for use with the PFC, PFC Sigma, Sigma TC3 Revision Knee, or S-ROM knee prosthesis in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention. These devices are for cemented use only.

The DePuy Universal Femoral Metaphyseal Sleeve and Universal Stem components are also intended for use with the DePuy LPS prosthesis for replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement. Specific diagnostic indications for use include: Malignant tumors (e.g., osteosarcomas, chondrosarcomas, gian cell tumors, bone tumors) requiring extensive resection and replacement; patient conditions of noninflammatory degenerative join disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g. rheumatoid arthritis, requiring extensive resection and replacement; revision for failed previous prosthesis cases requiring extensive resection and replacement. The LPS prosthesis is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.

The Universal Stem and the Universal Metaphyseal Sleeve components are intended for cemented use only.

DePuy Sigma PS Femoral Components and DePuy Sigma Cruciate Retaining (C/R) Porocoat Femoral Components

Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant.

Total knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total knee replacement outweighs the risks associated with the age of the patient, and if limited demands

regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to significant improvement in the quality of their lives.

THE SIGMA C/R POROCOAT® FEMORAL COMPONENTS ARE INTENDED FOR CEMENTED OR CEMENTLESS USE AS THE FEMORAL COMPONENT OF A TOTAL KNEE REPLACEMENT SYSTEM.

THE SIGMA PS FEMORAL COMPONENTS ARE INTENDED FOR CEMENTED USE AS THE FEMORAL COMPONENTS OF A TOTAL KNEE REPLACEMENT SYSTEM.

S-ROM™ NOILES™ Rotating Hinge Knee
The S-ROM NOILES Rotating Hinge Knee is indicated in cases for cement use in patients who have reached skeletal maturity and for whom the surgeon has decided to resect both cruciate ligaments due to the following conditions:
1. Severe instability, gross deformity and/or bone loss.
2. Failure of a previous knee reconstruction procedure.
3. Trauma or tumor resection.
4. Absent or markedly insufficient collateral ligaments.

DePuy P.F.C. ™ SIGMA™ Total Knee Prosthesis and DePuy SIGMA™ Total Knee Prosthesis
The DePuy SIGMA™ and P.F.C. ™SIGMA™ Total Knee Prosthesis are intended for use in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention.

The DePuy SIGMA™ and P.F.C. ™SIGMA™ Total Knee Prosthesis are intended for cement use only.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

510(K) SUMMARY

(As required by 21 CFR 807.92 and 21 CFR 807.93)

Contact Details	
Applicant Name	DePuy Ireland UC
Applicant Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Applicant & Correspondent Contact Telephone	574-400-6438
Applicant & Correspondent Contact	Meagan Robles
Applicant & Correspondent Contact Email	Mroble10@its.jnj.com
Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive Warsaw IN 46582 United States
Date prepared	April 11th, 2024
Name of device	
Trade or proprietary name	ATTUNE ™ Revision Knee System
Common or usual name	Total Knee Replacement Prosthesis
Classification name	21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3565 - Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	Class II - 21 CFR 888.3560, 21 CFR 888.3565
Product Code(s)	**JWH**: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer **MBH**: Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate**: K160700 – ATTUNE ™ Revision Knee System Reference Devices:

	K232303 – ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology K212746 & K230295 - ATTUNE Revision Cones K233980- ATTUNE Total Knee System, ATTUNE Knee System Cementless, LPS Limb Preservation System, Sigma High Performance (HP) Partial Knee System
Reason for 510(k) submission	In accordance with Section 510(k) of the Medical Device Amendments of 1976 and Subpart E of Part 807, Title 21 of the Code of Federal Regulations, and as per the FDA Guidance, Bundling Multiple Devices or Multiple Indications in a Single Submission: Guidance for Industry and FDA Staff (June 2007), DePuy Ireland UC has compiled a Bundled Traditional 510(k) Premarket Notification to modify labeling to include updated MRI compatibility information for DePuy ATTUNE™ Revision Knee System (K160700). Updates include modernizing and standardizing the language of the Instructions for Use (IFU) and labels.
Device description	A Total Knee Prosthesis is composed of individually packaged femoral, tibial and patellar components designed to replace the natural articular surface of the knee joint. The femoral component is a metal implant without a porous coating. The tibial component consists of a metal tibial base without porous coating, and a locking polyethylene insert. Some metal components have modular stems, porous and non porous-coated sleeves and/or modular augments. The patella component is an all polyethylene design Total knee arthroplasty may include supplemental fixation through stems, sleeves, and/or modular augments where bone loss requires said fixation in the opinion of the surgeon. Total knee arthroplasty may also include more constrained bearing surfaces where necessary to provide stability where musculoligamentous supporting structures are insufficient.
Intended use of the device	Total knee arthroplasty is a total joint replacement surgery designed to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. This includes severely disabled patients with multiple joint involvement for whom a gain in knee mobility may lead to an expectation of significant improvement in the quality of their lives.

Indications for use	Candidates for total knee replacement include patients with • A severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, or rheumatoid arthritis • Moderate valgus, varus, or flexion deformities • Avascular necrosis of the femoral condyle • A previous unsuccessful knee replacement, osteotomy, or other knee procedure ATTUNE Revision Knee System implants are designed for use in total knee arthroplasty for patients with: • Absence or loss of both cruciate ligaments • Moderate varus-valgus or flexion instability that requires a bearing surface with increased constraint in the clinical judgment of the surgeon • Bone loss that requires supplemental fixation in the clinical judgment of the surgeon The porous-coated metaphyseal sleeves are intended for either cemented or cementless applications. ANY NON POROUS-COATED COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY.
Substantial Equivalence	There are no changes in design, manufacturing, principle of operation, indication, or intended use. The only change is the addition of Magnetic Resonance (MR) safety information in the Instructions for Use (IFU) and the update of language in the IFU as discussed in **Performance Testing - Bench**.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

PERFORMANCE DATA

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

The following tests were performed (per FDA's *Testing and Labeling Medical Devices for Safety in the Magnetic*

Resonance (MR) Environment - Guidance for Industry and Food and Drug Administration Staff, October 2023) to determine Magnetic Resonance (MR) Safety:

ASTM F2503-23 - Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

ASTM F2182 -19E2 - Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance

ASTM F2052-21 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment ASTM F2213-17 - Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment ASTM F2119-07 - Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants The proposed devices also meet the requirement of bacterial endotoxin testing as specified in ANSI/AAMI ST 72:2019.
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
No clinical tests were conducted to demonstrate substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The subject DePuy ATTUNE Revision Knee System are substantially equivalent to the predicate ATTUNE Revision Knee System (K160700).

Contact Details	
Applicant Name	DePuy Ireland UC
Applicant Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Applicant & Correspondent Contact Telephone	574-400-6438
Applicant & Correspondent Contact	Meagan Robles
Applicant & Correspondent Contact Email	Mroble10@its.jnj.com
Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive Warsaw IN 46582 United States
Date prepared	April 11th, 2024
Name of device	
Trade or proprietary name	DePuy Knee Prosthesis System Universal Stem Extensions and Universal Femoral Metaphyseal Sleeves
Common or usual name	Tricompartmental Knee Prosthesis
Classification name	21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Class	II
Classification panel	87 Orthopedics
Regulation	Class II - 21 CFR 888.3560
Product Code(s)	**JWH**: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Legally marketed device(s) to which equivalence is claimed	Primary Predicate: K063633 - DePuy Knee Prosthesis System Universal Stem Extensions and Universal Femoral Metaphyseal Sleeves Reference Devices: K232303 – ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology K212746 & K230295 - ATTUNE Revision Cones K233980- ATTUNE Total Knee System, ATTUNE Knee System Cementless, LPS Limb Preservation System, Sigma High Performance (HP) Partial Knee System
Reason for 510(k) submission	In accordance with Section 510(k) of the Medical Device Amendments of 1976 and Subpart E of Part 807, Title 21 of the Code of Federal Regulations, and as per the FDA Guidance, Bundling Multiple Devices or Multiple Indications in a Single Submission: Guidance for Industry and FDA Staff (June 2007), DePuy Ireland UC has compiled a Bundled Traditional 510(k) Premarket Notification to modify labeling to include updated MRI compatibility information for DePuy Knee Prosthesis System Universal Stem Extensions and Universal Femoral Metaphyseal Sleeves (K063633). Updates include modernizing and standardizing the language of the Instructions for Use (IFU) and labels.
Device description	A Total Knee Prosthesis System is composed of individually packaged femoral, tibial and patellar components designed to replace the natural articular surface of the knee joint. The femoral component is a metal implant, with or without a porous coating. The tibial component may be an all polyethylene component or comprised of a metal tibial tray with or without porous coating, and a polyethylene insert and locking components. Some metal components have modular stems, sleeves and/or modular wedges. The patella component may be of an all polyethylene design or may be a metal backed polyethylene component. The wobble bit is an instrument used to aid implant assembly.
Intended use of the device	Total knee arthroplasty is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Indications for use	The DePuy Universal Femoral Metaphyseal Sleeve and Universal Stem components are intended for use with the PFC, PFC Sigma, Sigma TC3 Revision Knee, or S-ROM knee prosthesis in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention. These devices are for cemented use only. The DePuy Universal Femoral Metaphyseal Sleeve and Universal Stem components are also intended for use with the DePuy LPS prosthesis for replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement. Specific diagnostic indications for use include: Malignant tumors (e.g., osteosarcomas, chondrosarcomas, gian cell tumors, bone tumors) requiring extensive resection and replacement; patient conditions of noninflammatory degenerative join disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g. rheumatoid arthritis, requiring extensive resection and replacement; revision for failed previous prosthesis cases requiring extensive resection and replacement. The LPS prosthesis is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required. The Universal Stem and the Universal Metaphyseal Sleeve components are intended for cemented use only.
Substantial Equivalence	There are no changes in design, manufacturing, principle of operation, indication, or intended use. The only change is the addition of Magnetic Resonance (MR) safety information in the Instructions for Use (IFU) and the update of language in the IFU as discussed in **Performance Testing - Bench**.
SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE	
PERFORMANCE DATA	
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE	
The following tests were performed (per FDA's *Testing and Labeling Medical Devices for Safety in the Magnetic* *Resonance (MR) Environment - Guidance for Industry and Food and Drug Administration Staff, October 2023*) to determine Magnetic Resonance (MR) Safety: ASTM F2503-23 - Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	

ASTM F2182 -19E2 - Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance ASTM F2052-21 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment ASTM F2213-17 - Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment ASTM F2119-07 - Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants The proposed devices also meet the requirement of bacterial endotoxin testing as specified in ANSI/AAMI ST 72:2019.
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
No clinical tests were conducted to demonstrate substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The subject DePuy DePuy Knee Prosthesis System Universal Stem Extensions and Universal Femoral Metaphyseal Sleeves are substantially equivalent to the predicate DePuy Knee Prosthesis System Universal Stem Extensions and Universal Femoral Metaphyseal Sleeves (K063633).

Contact Details	
Applicant Name	DePuy Ireland UC
Applicant Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Applicant & Correspondent Contact Telephone	574-400-6438
Applicant & Correspondent Contact	Meagan Robles
Applicant & Correspondent Contact Email	Mroble10@its.jnj.com
Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive Warsaw IN 46582 United States
Date prepared	April 11th, 2024
Name of device	
Trade or proprietary name	DePuy Sigma PS Femoral Components

	DePuy Sigma Cruciate Retaining (C/R) Porocoat Femoral Components
Common or usual name	Total Knee System
Classification name	21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3565 - Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	Class II - 21 CFR 888.3560; 21 CFR 888.3565
Product Code(s)	**JWH**: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer **MBH**: Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate for DePuy Sigma PS Femoral Components:** K073529 – DePuy Sigma PS Femoral Components **Primary Predicate for DePuy Sigma Cruciate Retaining (C/R) Porocoat Femoral Components:** K062654 – DePuy Sigma Cruciate Retaining (C/R) Porocoat Femoral Components Reference Devices: K232303 – ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology K212746 & K230295 - ATTUNE Revision Cones K233980- ATTUNE Total Knee System, ATTUNE Knee System Cementless, LPS Limb Preservation System, Sigma High Performance (HP) Partial Knee System
Reason for 510(k) submission	In accordance with Section 510(k) of the Medical Device Amendments of 1976 and Subpart E of Part 807, Title 21 of the Code of Federal Regulations, and as per the FDA Guidance, Bundling Multiple Devices or Multiple Indications in a Single Submission: Guidance for Industry and FDA Staff (June 2007), DePuy Ireland UC has compiled a Bundled Traditional 510(k) Premarket Notification to modify labeling to include updated MRI compatibility information for DePuy Sigma PS Femoral Components (K073529) and DePuy Sigma Cruciate Retaining (C/R) Porocoat Femoral Components (K062654). Subject devices have similar indications and,

	therefore, have been combined within the same Instructions for Use (IFU). Additional, updates include modernizing and standardizing the language of the IFU and labels.
Device description	A SIGMA™ Total Knee System is composed of individually packaged femoral, tibial and patellar components designed to replace the natural articular surface of the knee joint. The femoral component is a metal implant, with or without a porous coating. The tibial component may be an all polyethylene component or comprised of a metal tibial tray with or without porous coating, and a polyethylene insert and locking components. Some metal components have modular stems, sleeves and/or modular wedges or augments. The patella component is an all polyethylene design.
Intended use of the device	Total knee arthroplasty is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.
Indications for use	Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant. Total knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to significant improvement in the quality of their lives. THE SIGMA C/R POROCOAT® FEMORAL COMPONENTS ARE INTENDED FOR CEMENTED OR CEMENTLESS USE AS THE FEMORAL COMPONENT OF A TOTAL KNEE REPLACEMENT SYSTEM. THE SIGMA PS FEMORAL COMPONENTS ARE INTENDED FOR CEMENTED USE AS THE FEMORAL COMPONENTS OF A TOTAL KNEE REPLACEMENT SYSTEM.
Substantial Equivalence	There are no changes in design, manufacturing, principle of operation, indication, or intended use.

	The only change is the addition of Magnetic Resonance (MR) safety information in the Instructions for Use (IFU) and the update of language in the IFU as discussed in **Performance Testing - Bench**.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

PERFORMANCE DATA

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

The following tests were performed (per FDA's *Testing and Labeling Medical Devices for Safety in the Magnetic*

Resonance (MR) Environment - Guidance for Industry and Food and Drug Administration Staff, October 2023) to determine Magnetic Resonance (MR) Safety:

ASTM F2503-23 - Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

ASTM F2182 -19E2 - Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance

ASTM F2052-21 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

ASTM F2213-17 - Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

ASTM F2119-07 - Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

The proposed devices also meet the requirement of bacterial endotoxin testing as specified in ANSI/AAMI ST 72:2019.

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

No clinical tests were conducted to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The subject DePuy Sigma PS Femoral Components and DePuy Sigma Cruciate Retaining (C/R) Porocoat Femoral Components are substantially equivalent to the predicate DePuy Sigma PS Femoral Components (K073529) and DePuy Sigma Cruciate Retaining (C/R) Porocoat Femoral Components (K062654).

Contact Details	
Applicant Name	DePuy Ireland UC
Applicant Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Applicant & Correspondent Contact Telephone	574-400-6438
Applicant & Correspondent Contact	Meagan Robles
Applicant & Correspondent Contact Email	Mroble10@its.jnj.com
Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive Warsaw IN 46582 United States
Date prepared	April 11th, 2024
Name of device	
Trade or proprietary name	S-ROM™ NOILES™ Rotating Hinge Knee System
Common or usual name	Tricompartmental Knee System
Classification name	21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	Class II - 21 CFR 888.3560
Product Code(s)	**JWH**: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Legally marketed device(s) to which equivalence is claimed	Primary Predicate: K896048- S-ROM/Noiles Mark 3 Secondary Predicates: K936037 - S-ROM NOILES Cruciate Retaining Knee K924940- Femoral & Tibial Augment Block, K905810- Noiles™ Total Knee Prosthesis, Modification, K870730- Noiles Total Knee Prosthesis Reference Devices: K232303 – ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology

	K212746 & K230295 - ATTUNE Revision Cones K233980- ATTUNE Total Knee System, ATTUNE Knee System Cementless, LPS Limb Preservation System, Sigma High Performance (HP) Partial Knee System
Reason for 510(k) submission	In accordance with Section 510(k) of the Medical Device Amendments of 1976 and Subpart E of Part 807, Title 21 of the Code of Federal Regulations, and as per the FDA Guidance, Bundling Multiple Devices or Multiple Indications in a Single Submission: Guidance for Industry and FDA Staff (June 2007), DePuy Ireland UC has compiled a Bundled Traditional 510(k) Premarket Notification to modify labeling to include updated MRI compatibility information for DePuy S-ROM™ NOILES™ Rotating Hinge Knee System (K936037, K924940, K905810, K896048, K870730). Updates include modernizing and standardizing the language of the Instructions for Use (IFU) and labels.
Device description	The S-ROM NOILES Rotating Hinge Knee System is a tricompartmental total knee replacement for both primary and revision cases. The S-ROM NOILES Rotating Hinge Knee System includes the femoral component with hinge pin, the tibial plateau assembly, and the distal femoral augmentation blocks. Replacement bumpers for the femoral component assembly and replacement hinge bearings for the tibial plateau assembly are also available.
Intended use of the device	The S-ROM NOILES Rotating Knee Hinge System is intended to provide a functional articulating knee joint in skeletally mature patients with a severely painful knee and impaired knee function and/or after a failed previous implant.
Indications for use	The S-ROM NOILES Rotating Hinge Knee is indicated in cases for cement use in patients who have reached skeletal maturity and for whom the surgeon has decided to resect both cruciate ligaments due to the following conditions: 1. Severe instability, gross deformity and/or bone loss. 2. Failure of a previous knee reconstruction procedure. 3. Trauma or tumor resection. 4. Absent or markedly insufficient collateral ligaments.
Substantial Equivalence	There are no changes in design, manufacturing, principle of operation, indication, or intended use.

	The only change is the addition of Magnetic Resonance (MR) safety information in the Instructions for Use (IFU) and the update of language in the IFU as discussed in **Performance Testing - Bench**.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

PERFORMANCE DATA

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

The following tests were performed (per FDA's *Testing and Labeling Medical Devices for Safety in the Magnetic*

Resonance (MR) Environment - Guidance for Industry and Food and Drug Administration Staff, October 2023) to determine Magnetic Resonance (MR) Safety:

ASTM F2503-23 - Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

ASTM F2182 -19E2 - Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance

ASTM F2052-21 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

ASTM F2213-17 - Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

ASTM F2119-07 - Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

The proposed devices also meet the requirement of bacterial endotoxin testing as specified in ANSI/AAMI ST 72:2019.

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

No clinical tests were conducted to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The subject DePuy S-ROM NOILES Rotating Hinge Knee are substantially equivalent to the predicate DePuy S-ROM™ NOILES™ Rotating Hinge Knee System (K896048, K936037, K924940, K905810, K870730).

Contact Details	
Applicant Name	DePuy Ireland UC
Applicant Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND

Applicant & Correspondent Contact Telephone	574-400-6438
Applicant & Correspondent Contact	Meagan Robles
Applicant & Correspondent Contact Email	Mroble10@its.jnj.com
Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive Warsaw IN 46582 United States
Date prepared	April 11th, 2024
Name of device	
Trade or proprietary name	DePuy P.F.C. ™ SIGMA™ Total Knee Prosthesis DePuy SIGMA™ Total Knee Prosthesis
Common or usual name	Tricompartmental Knee Prosthesis
Classification name	21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	Class II - 21 CFR 888.3560
Product Code(s)	**JWH**: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Legally marketed device(s) to which equivalence is claimed	**<u>DePuy P.F.C. ™ SIGMA™ Total Knee Prosthesis</u>** **Primary Predicate for DePuy P.F.C. ™ SIGMA™ Total Knee Prosthesis:** K060515- DePuy P.F.C. SIGMA Knee Prosthesis **Secondary Predicates for DePuy P.F.C. ™ SIGMA™ Total Knee System:** K984158- DePuy P.F.C. Modular Plus Offset Tibial Trays, K971189- DePuy P.F.C. ™ SIGMA™ Knee System (SIZE 1.5) , K971652- PFC Sigma Knee System Inset Patella K963117- P.F.C. Sigma Knee System (Stabilized Plus) K961685- P.F.C. Cruciate Retaining Knee System (Size 1.5),

	K950010- Darwin Knee System (Cruciate Substituting) Porous coated and Non-Porous Coated K952830- Darwin Knee System K943462- Darwin Knee System K923807- P.F.C. Modular Total Knee System, Modular Plus K884796- P.F.C. Modular Knee K882234- Johnson & Johnson Modular Total Knee Prosthesis **DePuy Sigma Total Knee Prosthesis** **Primary Predicate for DePuy Sigma Total Knee Prosthesis:** K040166 - DePuy Sigma XLK Tibial Inserts **Secondary Predicates for DePuy Sigma Total Knee Prosthesis:** K033272 - DePuy Sigma Tibial Inserts K032151 -DePuy Sigma Co-Cr Tibial Trays Reference Devices: K232303 – ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology K212746 & K230295 - ATTUNE Revision Cones K233980- ATTUNE Total Knee System, ATTUNE Knee System Cementless, LPS Limb Preservation System, Sigma High Performance (HP) Partial Knee System
Reason for 510(k) submission	In accordance with Section 510(k) of the Medical Device Amendments of 1976 and Subpart E of Part 807, Title 21 of the Code of Federal Regulations, and as per the FDA Guidance, Bundling Multiple Devices or Multiple Indications in a Single Submission: Guidance for Industry and FDA Staff (June 2007), DePuy Ireland UC has compiled a Bundled Traditional 510(k) Premarket Notification to modify labeling to include updated MRI compatibility information for DePuy P.F.C. ™ SIGMA™ Total Knee Prosthesis (K060515, K984158 , K971189, K971652, K963117, K961685, K950010, K952830, K943462, K923807, K884796, K882234) and DePuy SIGMA™ Total Knee Prosthesis (K040166, K033272, K032151). Updates include modernizing and standardizing the language of the Instructions for Use (IFU) and labels.

Device description	The DePuy SIGMA™ and P.F.C.™ SIGMA® Total Knee Prosthesis is a total knee prosthesis composed of individually packaged femoral, tibial base, tibial insert and patellar components designed to replace the natural articular surface of the knee joint or after a failed previous implant. Some femoral and tibial components can be used with modular stems, porous and non-porous coated sleeves and/or modular augments when supplemental fixation is required in the judgement of the surgeon. The natural patella may or may not be resurfaced.
Intended use of the device	The DePuy SIGMA and P.F.C SIGMA Total Knee Prosthesis is intended to replace articulating elements of a damaged knee joint where there is evidence of sufficient sound bone to seat and support the components.
Indications for use	The DePuy SIGMA™ and P.F.C. ™SIGMA™ Total Knee Prosthesis are intended for use in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention. The DePuy SIGMA™ and P.F.C. ™SIGMA™ Total Knee Prosthesis are intended for cement use only.
Substantial Equivalence	There are no changes in design, manufacturing, principle of operation, indication, or intended use. The only change is the addition of Magnetic Resonance (MR) safety information in the Instructions for Use (IFU) and the update of language in the IFU as discussed in **Performance Testing - Bench**.
SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE	
PERFORMANCE DATA	
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE	
The following tests were performed (per FDA's *Testing and Labeling Medical Devices for Safety in the Magnetic* *Resonance (MR) Environment - Guidance for Industry and Food and Drug Administration Staff, October 2023*) to determine Magnetic Resonance (MR) Safety:	

ASTM F2503-23 - Standard practice for marking medical devices and other items for safety in the magnetic resonance environment ASTM F2182 -19E2 - Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance ASTM F2052-21 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment ASTM F2213-17 - Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment ASTM F2119-07 - Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants The proposed devices also meet the requirement of bacterial endotoxin testing as specified in ANSI/AAMI ST 72:2019.
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
No clinical tests were conducted to demonstrate substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The subject DePuy P.F.C. ™ SIGMA™ Total Knee Prosthesis and DePuy SIGMA™ Total Knee Prosthesis are substantially equivalent to the predicate DePuy P.F.C. ™ SIGMA™ Total Knee Prosthesis (K060515, K984158, K971189, K971652, K963117, K961685, K950010, K952830, K943462, K923807, K884796, K882234) and DePuy SIGMA™ Total Knee Prosthesis (K040166, K033272, K032151).