March 21, 2024

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

Re: K233980
Trade/Device Name: ATTUNE Total Knee System, ATTUNE Cementless Knee System, LPS Limb Preservation System, Sigma High Performance (HP) Partial Knee System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO, OIY, MBH, JWH, NPJ, HRY, KRR
Dated: December 15, 2023
Received: December 18, 2023

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

Submission Number *(if known)*

K233980

Device Name

ATTUNE™ Total Knee System;
ATTUNE™ Cementless Knee System ;
LPS™ Limb Preservation System;
Sigma™ High Performance (HP) Partial Knee System

Indications for Use *(Describe)*

ATTUNE™ Total Knee System 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.

ATTUNE™ Cementless Knee System Indications for Use
The ATTUNE™ Cementless CR and PS Femoral Components are intended for cementless use within the ATTUNE™ Total Knee Replacement System.
Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, or a failed previous implant (provided that adequate bone is present).

LPS™ Limb Preservation System Indications for Use
The DePuy LPS System is intended for use in 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, giant cell tumors, bone tumors) requiring extensive resection and replacement;
• patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement;
• revision cases for a failed previous prosthesis requiring extensive resection and replacement;
• severe trauma requiring extensive resection and replacement.
The LPS System is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.
The S-ROM tibial tray and the non-porous coated straight and bowed stems are intended for cemented use only.
The porous-coated metaphyseal sleeves are intended for either cemented or cementless applications.

Sigma™ High Performance (HP) Partial Knee System Indications for Use
The SIGMA™ High Performance Partial Knee System is indicated for single compartmental knee replacement in skeletally mature individuals with osteoarthritis, post-traumatic arthritis of the tibiofemoral surfaces or a history of gout or pseudogout. All components are intended for CEMENTED 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.

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 Contact Telephone	574-400-6438
Applicant Contact	Meagan Robles
Applicant Contact Email	Mroble10@its.jnj.com
Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive Warsaw IN 46582 United States
Correspondent Contact Telephone	574-400-6438
Correspondent Contact	Meagan Robles
Correspondent Contact Email	Mroble10@its.jnj.com
Date prepared	December 21, 2023
Name of device	
Trade or proprietary name	Attune ™ Total 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
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 **OIY**: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive
Legally marketed device(s) to which equivalence is claimed	Primary Predicate: K111433 - DePuy Attune ™ Knee System Secondary Predicate: K170806 – ATTUNE Cemented Tibial Base, Fixed Bearing 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
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™ Total Knee System (K111433, K170806). 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 may be an all polyethylene component or comprised of a metal tibial base without porous coating, and a polyethylene insert and locking components. The patella component may be of 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. 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 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, rheumatoid arthritis, or a failed previous implant.
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 Total Knee System are substantially equivalent to the predicate ATTUNE Total Knee System (K111433, K170806).

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

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Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive Warsaw IN 46582 United States
Correspondent Contact Telephone	574-400-6438
Correspondent Contact	Meagan Robles
Correspondent Contact Email	Mroble10@its.jnj.com
Date prepared	December 21, 2023
Name of device	
Trade or proprietary name	ATTUNE ™ Cementless Knee System
Common or usual name	Total Knee Prosthesis
Classification name	21 CFR 888.3565 - Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	Class II - 21 CFR 888.3565
Product Code(s)	**MBH**: Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer **JWH**: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Legally marketed device(s) to which equivalence is claimed	Primary Predicate: K140881 - ATTUNE ™ Knee System- Cementless CR and PS 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
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™ Cementless Knee System (K140881). 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 with or without a porous coating. The tibial component may be an all polyethylene component or comprised of a metal tibial base without porous coating, and a polyethylene insert and locking components. The patella component may be of 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. 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 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	The ATTUNE™ Cementless CR and PS Femoral Components are intended for cementless use within the ATTUNE™ Total Knee Replacement System. Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, or a failed previous implant (provided that adequate bone is present).
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 Cementless Knee System are substantially equivalent to the predicate ATTUNE Knee System – Cementless (K140881).

Contact Details	
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Applicant Contact	Meagan Robles
Applicant Contact Email	Mroble10@its.jnj.com

Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive Warsaw IN 46582 United States
Correspondent Contact Telephone	574-400-6438
Correspondent Contact	Meagan Robles
Correspondent Contact Email	Mroble10@its.jnj.com
Date prepared	December 21, 2023
Name of device	
Trade or proprietary name	LPS - Limb Preservation System
Common or usual name	Total Femur Replacement Prosthesis Proximal Tibial Replacement Prosthesis
Classification name	21 CFR 888.3510 - Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis 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 888.3510; 21 CFR 888.3560; 21 CFR 888.3365
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 **KRO**: Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer
Legally marketed device(s) to which equivalence is claimed	Primary Predicate: K091453 – DePuy LPS Universal Hinge Insert Assembly Secondary Predicates: K033959 – LPS ; K003182 – Orthogenesis LPS 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
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 modernize and standardize the language of the Instructions for Use (IFU) and labels with continued use of "Safety in MRI not evaluated" unknownfor DePuy LPS™- Limb Preservation System (K091453, K033959, K003182).
Device description	The DePuy LPS™ Limb Preservation System is designed for the replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia. The DePuy LPS system offers a variety of component options (including, but not limited to, proximal femoral bodies, segmental components, distal femoral components, femoral stems, tibial stems, proximal tibial components, hinged tibial insert bearings, metaphyseal sleeves, and adapters). The components, which can be used in conjunction with certain components from other systems, are for treatment of patients presenting bone loss and deformity associated with bone tumors resection, trauma, infection, and difficult revision arthroplasty. A total femoral replacement is possible in those cases where no part of the femur can be salvaged.
Intended use of the device	The DePuy LPS System is intended for use in 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.
Indications for use	The DePuy LPS System is intended for use in 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, giant cell tumors, bone tumors) requiring extensive resection and replacement; • patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement; • revision cases for a failed previous prosthesis requiring extensive resection and replacement; • severe trauma requiring extensive resection and replacement. The LPS System is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.

	The S-ROM tibial tray and the non-porous coated straight and bowed stems are intended for cemented use only. The porous-coated metaphyseal sleeves are intended for either cemented or cementless applications.
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 LPS Limb Preservation System are substantially equivalent to the predicate LPS Limb Preservation System (K091453, K033959, K003182).

Contact Details	
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Applicant Contact	Meagan Robles
Applicant Contact Email	Mroble10@its.jnj.com
Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive Warsaw IN 46582 United States
Correspondent Contact Telephone	574-400-6438
Correspondent Contact	Meagan Robles
Correspondent Contact Email	Mroble10@its.jnj.com
Date prepared	December 21, 2023
Name of device	
Trade or proprietary name	Sigma High Performance (HP) Partial Knee System
Common or usual name	Compartmental Knee Prosthesis System
Classification name	21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3530 - Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	Class II - 21 CFR 888.3560; 21 CFR 888.3530
Product Code(s)	**NPJ**: Prosthesis, Knee Patellofemorotibial, Partial, Semi-Constrained, Cemented, Polymer/Metal/Polymer **HRY**: Prosthesis, Knee, Femorotibial, Semi-Constrained, Cemented, Metal/Polymer **KRR**: Prosthesis, Knee, Patello/Femoral, Semi-Constrained, Cemented, Metal/Polymer
Legally marketed device(s) to which equivalence is claimed	Primary Predicate: K070267 - Sigma High Performing Unity Knee Resurfacing Secondary Predicates: K070849 - DePuy GCK Femoral and Tibial Components;

	K061648 - DePuy Graduated Compartmental Knee (GCK) 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
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 Sigma™ High Performance (HP) Partial Knee System (K070267, K070849, K061648). Updates include modernizing and standardizing the language of the Instructions for Use (IFU) and labels.
Device description	The DePuy SIGMA™ High Performance Partial Knee System is a single compartmental knee prosthesis, composed of individually packaged femoral, and tibial components designed to be used in various combinations to replace the natural articular surfaces of the knee joint. The unicompartmental femoral components are Co-Cr-Mo metal implants. The metal backed tibial components are Co-Cr-Mo with polyethylene inserts. The all-polyethylene unicompartmental tibial component are manufactured from polyethylene. The unicompartmental femoral components are designed for individuals who require a higher than normal degree of flexion (up to 155º).
Intended use of the device	The DePuy SIGMA High Performance Partial Knee System is intended to provide increased patient mobility and reduced pain by replacing the articulating elements of a single compartment of a damaged knee joint in patients where there is evidence of sufficient sound bone to seat and support the components.
Indications for use	The SIGMA High Performance Partial Knee System is indicated for single compartmental knee replacement in skeletally mature individuals with osteoarthritis, post-traumatic arthritis of the tibiofemoral surfaces or a history of gout or pseudogout. All 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 Sigma High Performance (HP) Partial Knee System are substantially equivalent to the predicate Sigma High Performance Unity Knee System (K070267, K070849, K061648).