November 19, 2025

DePuy Ireland UC
Hannah Foley
Director, Regulatory Affairs
Loughbeg
Ringaskiddy, Cork P43 ED82
Ireland

Re: K253197
Trade/Device Name: ATTUNE™ Total Knee System; ATTUNE™ Revision Sleeve LPS™ Femoral Adaptors
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, OIY
Dated: September 26, 2025
Received: September 26, 2025

Dear Hannah Foley:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

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

K253197

Please provide the device trade name(s).

ATTUNE™ Total Knee System;
ATTUNE™ Revision Sleeve LPS™ Femoral Adaptors

Please provide your Indications for Use below.

ATTUNE™ Total Knee System
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™ Revision Sleeve LPS™ Femoral Adaptors
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.

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

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

510(K) SUMMARY
(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	850-251-9921
Applicant & Correspondent Contact	Sierra Robinson
Applicant & Correspondent Contact Email	Srobin24@its.jnj.com
Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive Warsaw IN 46582 United States
Date prepared	October 1, 2025
Name of device	
Trade or proprietary name	ATTUNE ™ Total Knee System
Common or usual name	Total Knee Replacement Prothesis
Classification name	21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3565 - Knee joint patellofemorotibial polymer/metal porous coated uncemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	Class II - 21 CFR 888.3560, 21 CFR 888.3565, 21 CFR 888.3560
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 **OIY**: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive

Legally marketed device(s) to which equivalence is claimed	**Primary Predicate**: K211609 ATTUNE ™ Medial Stabilized Fixed Bearing (MS FB) Inserts **Reference Devices:** K233980 MRI Bundle – ATTUNE, LPS, Sigma HP Uni
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. 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.
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. 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, or 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 for the subject device by consolidating system specific Instructions for Use (IFU) which have the MRI language 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 ATTUNE ™ Total Knee System are substantially equivalent to the predicate ATTUNE ™ Medial Stabilized Fixed Bearing (MS FB) Inserts (K211609).

Contact Details	
Applicant Name	DePuy Ireland UC
Applicant Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Applicant & Correspondent Contact Telephone	850-251-9921
Applicant & Correspondent Contact	Sierra Robinson
Applicant & Correspondent Contact Email	Srobin24@its.jnj.com

Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive Warsaw IN 46582 United States
Date prepared	October 1, 2025
Name of device	
Trade or proprietary name	ATTUNE ™ Revision Sleeve LPS™ Femoral Adaptors
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 polymer/metal 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**: K202248 ATTUNE ™ Revision Sleeve LPS™ Femoral Adaptors **Reference Devices:** K241000 MRI Bundled - 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
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 Sleeve LPS™ Femoral Adaptors . Updates include modernizing and standardizing the language of the Instructions for Use (IFU) and labels.
Device description	The ATTUNE™ Revision Sleeve LPS™ Femoral Adaptors are designed as a component in the replacement of the natural articular surface of the knee joint or of

	the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia. The ATTUNE Revision Sleeve LPS Femoral Adaptors are to be used to connect an ATTUNE Revision Femoral Sleeve to LPS System Components.
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. 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.
Indications for use	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.
Substantial Equivalence	There are no changes in design, manufacturing, principle of operation, indication, or intended use. The only change is the update of Magnetic Resonance (MR) safety information 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 ATTUNE ™ Revision Sleeve LPS™ Femoral Adaptors are substantially equivalent to the predicate ATTUNE ™ Revision Sleeve LPS™ Femoral Adaptors (K202248).