November 21, 2024

DePuy Ireland UC
c/o Paige Myers
Regulatory Affairs Specialist II
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K242871
Trade/Device Name: ATTUNE™ Revision Hinge Knee
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: September 20, 2024
Received: September 23, 2024

Dear Paige Myers:

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2024.11.21 12:31:58 -05'00'

for: Lixin Liu
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)*

K242871

Device Name

ATTUNE™ Revision Hinge Knee

Indications for Use *(Describe)*

The ATTUNE Revision 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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

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

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Establishment Registration Number	3015516266
Name of contact person	Paige Myers
E-Mail Address	pmyers1@its.jnj.com and DePuySynthesJointsRegulatoryAffairs@its.jnj.com
Alternate Contact Person	Michael Liao
Alternate Contact E-Mail	mliao7@its.jnj.com
Alternate Contact Phone	+1 925 8901497
Date prepared	7 October 2024
Name of device	
Trade or proprietary name	ATTUNE™ Revision Hinge Knee
Common or usual name	Total Hinge Knee System
Classification name	21 CFR 888.3510 – Knee joint femorotibial metal/polymer constrained cemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	Class II - 21 CFR 888.3510
Product Code(s)	**KRO:** Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate Device:** K896048 – S-ROM/Noiles Mark 3 **Secondary Predicate Device**: K091453 – DePuy LPS Universal Hinge Insert Assembly **Reference Predicate Device**: K160700 – ATTUNE™ Revision Knee System K983014 – Summit Acetabular System
Reason for 510(k) submission	Pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in accordance with 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 Format for Traditional and Abbreviated 510(k)s: Guidance for Industry and Food and Drug Administration Staff (2019), DePuy Ireland UC has compiled a Traditional 510(k) Premarket Notification to obtain market clearance for the ATTUNE Revision Hinge Knee.

Device description	The ATTUNE™ Revision Hinge Knee, comprised of a femoral, housing assembly, and tibial insert component, is compatible with devices of the ATTUNE Knee System and the ATTUNE Revision Knee System and is designed to replace the natural articulating surface of the knee joint in total knee arthroplasty. The femoral component is a metal/ultra-high molecular weight polyethylene (UHMWPE) implant intended for cemented use. The housing assembly component is composed of both metal and antioxidant (AOX) UHMWPE subcomponents. The tibial insert component is composed of AOX UHMWPE.
Intended use of the device	The ATTUNE Revision Knee Hinge 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 ATTUNE Revision 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

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE				
The ATTUNE Revision Hinge Knee is substantially equivalent to its primary predicate S-ROM/Noiles Mark 3 (K896048) and secondary predicate LPS Universal Hinge Insert (K091453). The primary and secondary predicates must be used together to form a rotating hinge knee construct, similar to the rotating hinge knee construct formed by the components of the ATTUNE Revision Hinge Knee. In addition, the subject ATTUNE Revision Hinge Knee and a reference predicate, the ATTUNE Revision Knee System (K160700) are very similar in device geometry and design features. The reference predicate device ATTUNE Revision Knee System is not a rotating hinge knee construct but, is the compatible knee system for the subject device.				
Characteristics	**Subject Device: ATTUNE Revision Hinge Knee**	**Primary Predicate Device: S-ROM/Noiles Mark 3 K896048**	**Secondary Predicate Device: LPS Universal Hinge Insert K091453**	**Reference Predicate Device: ATTUNE Revision Knee System K160700**
Indications for Use	The ATTUNE Revision 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	The Noiles (Mark 3) Rotating Hinge Knee System is indicated for severe instability, gross deformity and/or bone loss resulting from: 1. failure of a previous prosthesis, 2. trauma or tumor resection, 3. absent or markedly insufficient collateral ligaments The Noiles (Mark 3) Rotating Hinge Knee System is intended for cement 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: 1. malignant tumors (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection and replacement; 2. 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; 3. revision cases for a failed previous prosthesis requiring extensive resection and replacement; 4. severe trauma requiring extensive resection and replacement	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

			5. 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.	clinical judgment of the surgeon The porous-coated metaphyseal sleeves are intended for either cemented or cementless applications.
Material	Cobalt Chrome alloy, AOX UHMWPE	Cobalt Chrome alloy	UHMWPE, Cobalt Chrome alloy	Cobalt Chrome alloy, AOX UHMWPE
Fixation	Cemented	Cemented	N/A	Cemented, Cementless
Femur Sizes	3 through 8 (Lefts & Rights)	XSmall, Small, Medium (Lefts & Rights)	N/A	1 through 10 (Lefts & Rights)
Tibia Insert Sizes	Sizes: 3 through 8 Thicknesses (mm) 8 through 26 (increasing by 2mm)	N/A	Sizes: XSmall, Small, Medium Thickness (mm): 12,14,16,18,21,23,26,28,31	Sizes: 1 through 10 Thicknesses (mm): 6 through 26 (increasing by 2mm)
Housing Assembly	Same as Predicates	Axel and Hinge Post Assembly	Axel and Hinge Post Assembly	N/A
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	10^{-6}
Sterile Method	Gamma Radiation	Gamma Radiation	Gamma Radiation	Gamma Radiation
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 following tests were performed in support of the ATTUNE Revision Hinge Knee to demonstrate substantial equivalence of safety and efficacy with the predicate devices: • Shear Testing • Fatigue Testing • Wear Performance • Stability Testing • Contact Pressure Testing • Biocompatibility • MRI Safety Evaluation Testing The ATTUNE Revision Hinge Knee is substantially equivalent to its primary predicate S-ROM/Noiles Mark 3 (K896048) and secondary predicate LPS Universal Hinge Insert (K091453).