DePuy Ireland UC
℅ Soraya Hori
Project Leader Regulatory Affairs
Depuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K202248
Trade/Device Name: 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
Dated: November 13, 2020
Received: November 16, 2020

Dear Soraya Hori:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for

Ting Song, Ph.D., R.A.C.
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K202248

Device Name
ATTUNE® Revision Sleeve LPS™ Femoral Adaptors

Indications for Use *(Describe)*
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.

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)

*Table 1: 510(K) Summary*

| **Submitter Information** | |
|---|---|
| Name | DePuy Ireland UC |
| Address | Loughbeg, Ringaskiddy<br>Co. Cork Munster, IRELAND |
| Phone number | 574-372-7491 |
| Fax number | 574- 371-4987 |
| Establishment Registration Number | 3015516266 |
| Name of contact person | Soraya L. Hori |
| Date prepared | August 7, 2020 |
| **Name of device** | |
| **Trade or proprietary name** | ATTUNE® Revision Sleeve LPS™ Femoral Adaptors |
| **Common or usual name** | Total Knee Replacement Prosthesis |
| **Classification name** | Knee joint patellofemorotibial<br>polymer/metal/polymer semiconstrained<br>cemented prosthesis<br><br>Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis |
| **Class** | II |
| **Classification panel** | 87 Orthopedics |
| **Regulation** | 21 CFR 888.3560, 21 CFR 888.3565 |
| **Product Code(s)** | JWH, MBH |
| **Legally marketed device(s) to which equivalence is claimed** | Primary: K071417 Limb Preservation System Diaphyseal and Metaphyseal Sleeves<br>Reference: K040281 Limb Preservation System Metaphyseal Sleeves |
| **Reason for 510(k) submission** | The purpose of this submission is for the addition of a new adaptor option to the DePuy Knee Revision portfolio. |
| **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. |
| **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;<br>• 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;<br>• revision cases for a failed previous prosthesis requiring extensive resection and replacement;<br>• severe trauma requiring extensive resection and replacement.<br>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.<br>The S-ROM tibial tray and the non-porous coated straight and bowed stems are intended for cemented use only.<br>The porous-coated metaphyseal sleeves are intended for either cemented or cementless applications. |

*Table 2:* Subject Device compared to Predicate Device

| Characteristics | Subject Device: ATTUNE Revision Sleeve LPS Femoral Adaptor | Predicate Device: LPS Femoral To Sleeve Adapter K071417 (Primary), K040281 (Reference) |
|---|---|---|
| **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:<br>•malignant tumors (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection and replacement;<br>• 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;<br>• revision cases for a failed previous prosthesis requiring extensive resection and replacement;<br>• severe trauma requiring extensive resection and replacement.<br>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.<br>The S-ROM tibial tray and the non-porous coated straight and bowed stems are intended for cemented use only.<br>The porous-coated metaphyseal sleeves are intended for either cemented or cementless applications. | 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:<br>• malignant tumors (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection and replacement;<br>• 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;<br>• revision cases for a failed previous prosthesis requiring extensive resection and replacement;<br>• severe trauma requiring extensive resection and replacement.<br>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.<br>The S-ROM tibial tray and the non-porous coated straight and bowed stems are intended for cemented use only.<br>The porous-coated metaphyseal sleeves are intended for either cemented or cementless applications. |
| **Material** | Wrought, low carbon, cobalt chrome molybdenum alloy | Wrought High-Carbon Co-Cr-Mo Bar or Wrought, Low Carbon, Cobalt, Molybdenum Bar |
| **Locking Design/Mating Design** | Taper Lock | Taper Lock |
| **Offset height options** | +0MM, +5MM, +10MM | +0MM, +5MM, +10MM |
| **Sterilization Method** | Gamma Radiation | Gamma Radiation |
| **Packaging** | Polyurethane protective component sealed in two Tyvek-lidded PETG blister trays, packaged with an IFU and label stock, all contained in a folding carton with shrink wrap. | Polyurethane protective component sealed in two Tyvek-lidded PETG blister trays, packaged with an IFU and label stock, all contained in a folding carton with shrink wrap. |
| **Shelf Life** | 10 years | 10 years |

The subject device, ATTUNE Revision Sleeve LPS Femoral Adaptor, has the same intended use, indications for use, material, and locking mechanism as the predicate device, LPS Universal Femoral to Sleeve Adapter. The ATTUNE Revision Sleeve LPS Femoral Adaptor is designed to mate with a different femoral sleeve than the LPS Universal Femoral to Sleeve Adapter. The ATTUNE Revision Sleeve LPS Femoral Adaptor was tested for taper connections tension and torsion strength. It was found to be equivalent to the LPS Universal Femoral to Sleeve Adaptor.

**PERFORMANCE DATA**

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

The following tests were performed on the ATTUNE Revision Sleeve LPS Femoral Adaptor to demonstrate substantial equivalence of safety and efficacy with the predicate device:

- taper connections tension and torsion strength
- biocompatibility testing

Magnetic Resonance Imaging safety evaluation testing was performed, and the tests evaluated the worst-case components and constructs for magnetically induced force, torque, image artifact and RF heating. The testing concluded that there are no safety issues related to magnetic field interactions under specific conditions identified in the labeling.

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**

Clinical testing was not required to demonstrate substantial equivalence.

**CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA**

The subject DePuy ATTUNE Revision Sleeve LPS Femoral Adaptor are substantially equivalent to the predicate LPS Universal Femoral to Sleeve Adapter (K040281, K071417).