DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 10, 2016

DePuy Orthopaedics Incorporated
Soraya Hori
Regulatory Affairs Associate
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K160700
Trade/Device Name: ATTUNE® Revision Knee System
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: March 10, 2016
Received: March 14, 2016

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): K160700

Device Name: ATTUNE® Revision 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, 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.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(K) SUMMARY

Submitter:
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46582

Establishment Registration Number: 1818910

Contact Person:
Soraya L. Hori
Sr. Regulatory Affairs Associate
Phone: (574) 372-7491
Fax: (574) 371-4987

Date Prepared: March 10, 2016

Proprietary Name: ATTUNE® Revision Knee System

Common 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

Product Codes: JWH, MBH

Predicate Devices: The ATTUNE Revision Knee System components are substantially equivalent to legally marketed devices including:

Primary Predicates:
- ATTUNE Total Knee System (Posterior Stabilized) –K111433*
- Darwin Knee System (TC3) – K952830**

Reference Predicates:
- ATTUNE Total Knee System (Cruciate Retaining) –K101433*
- SIGMA Co-Cr Tibial Trays – K032151**
- Universal Knee Stem Extensions and Universal Metaphyseal Sleeves – K063633**
- PFC Modular Plus Tibial Wedge – K923807**
- DePuy SIGMA Knee Prosthesis – K060515**
- DePuy LPS Metaphyseal Sleeves –K071417
- SROM Noiles PS Total Knee System – K941769
- Triathlon® TS Knee System – K070095

*These 510(k)s are encompassed within the ATTUNE Total Knee Product Family.
** These 510(k)s are encompassed within the SIGMA Product Family.

Device Description:

ATTUNE REVISION CRS FEMORAL COMPONENTS:

The ATTUNE Constrained Revision System (CRS) Femoral Components are manufactured from cast Co-Cr-Mo alloy conforming to ASTM F75. The ATTUNE Revision CRS Femoral Components have an asymmetric trochlear groove and are available in sizes 1 to 10 in both right and left options. The components contain a fixed boss to allow attachment of the ATTUNE Revision Femoral Sleeves or the ATTUNE Revision Stems. Augment holes are also present to allow attachment of the ATTUNE Revision Femoral Augments. The ATTUNE Revision CRS Femoral Components have recessed cement pockets and a textured fixation surface. A removable plug made of Ultra High Molecular Weight Polyethylene (UHMWPE) conforming to ASTM F648 is pre-assembled in the stem boss.

ATTUNE REVISION CRS FIXED BEARING INSERTS:

The ATTUNE Revision CRS Fixed Bearing Tibial Inserts articulate with the ATTUNE Revision CRS Femoral Components. The UHMWPE Antioxidant (AOX) Tibial Inserts are manufactured from raw materials conforming to ASTM F648 and are available in sizes 1 to 10 and in thicknesses of 6, 8, 10, 12, 14, 16, 18, 20, 22, 24 and 26mm.

ATTUNE REVISION FIXED BEARING TIBIAL BASES:

The ATTUNE Revision Fixed Bearing Tibial Bases are manufactured from cast Co-Cr-Mo alloy conforming to ASTM F75 and includes a Ti-6Al-4V removable end cap. The Tibial Bases are available in sizes 1 to 10. Augment holes are also present to allow attachment of the ATTUNE Revision Tibial Augments. The ATTUNE Revision Fixed Bearing Tibial Bases fixation surface is textured. It incorporates a stem and keel for additional stability and recessed cement pockets for cement fixation. The ATTUNE Revision Fixed Bearing Tibial Bases utilize a central, universal locking mechanism that engages anterior and posterior tabs in the Tibial Insert. Additionally, the ATTUNE Revision Fixed Bearing Tibial Bases have a Base Protector assembled with the device to minimize potential marring of the proximal bearing surface of the component during impaction. After impaction is completed, the Base Protector is then removed and discarded prior to inserting the ATTUNE Revision CRS Fixed Bearing Inserts.

ATTUNE REVISION STEMS:

The ATTUNE Revision Cemented and Press-fit Stems are manufactured from Ti-6Al-4V ELI alloy conforming to ASTM F136. The ATTUNE Revision Stems are optional components that may be used to provide additional fixation of the knee prosthesis construct and are compatible with the ATTUNE Revision CRS Femoral, ATTUNE Revision Fixed Bearing Tibial Base, ATTUNE Revision Offset Adaptor, and the ATTUNE Revision Femoral Sleeve components. All ATTUNE Revision Stems utilize a threaded junction with mating components. The ATTUNE Revision Press-fit Stems are cross-slotted and are designed with a cone-shaped distal tip to facilitate insertion into the medullary canal of the distal femur or proximal tibia. The ATTUNE Cemented Stems are designed with a cylindrical or tapered body geometry depending on length and recessed cement pockets. The fixation surface is blasted and fluted.

ATTUNE REVISION FEMORAL SLEEVES:

The ATTUNE Revision Femoral Sleeves are manufactured from Ti-6Al-4V alloy conforming to ASTM F620 or ASTM F136. The ATTUNE Revision Femoral Sleeve is an optional component intended to provide improved fit of the femoral prosthesis where the metaphyseal bone in the distal femur is either absent or of poor quality. The Sleeve has a symmetric taper geometry with steps in the body to provide initial fixation and bone loading. There are six component sizes - 30, 35, 40, 45, 50 and 55mm - and are available in non-porous cemented (30mm only), partially porous coated, or fully porous coated. The ATTUNE Revision Femoral Sleeves utilize a locking taper to attach to the ATTUNE Revision CRS Femoral Component and a threaded junction with the ATTUNE Revision Stem components. A removable plug manufactured from UHMWPE conforming to ASTM F-648 is pre-assembled to the sleeve component.

ATTUNE REVISION FEMORAL AUGMENTS:

The ATTUNE Revision Femoral Augments are designed to build up the distal and/or posterior interior surfaces to accommodate bony insufficiency and aid in flexion/extension gap balancing. The augments are manufactured from cast Co-Cr-Mo conforming to ASTM F75 and are available in sizes 1 to 10 with varying thicknesses depending on size. Each augment attaches to either the distal or posterior interior surface of the ATTUNE Revision CRS Femoral Component.

ATTUNE REVISION TIBIAL AUGMENTS:

The ATTUNE Revision Tibial Augments are manufactured from wrought Co-Cr-Mo alloy conforming to ASTM F1537 or cast Co-Cr-Mo alloy conforming to ASTM F75 or forged Co-Cr-Mo alloy conforming to ASTM F799 and are available from sizes 1 to 10 and in thicknesses of 5, 10, and 15mm. The Tibial Augments are designed to be compatible with the ATTUNE Revision Fixed Bearing Tibial Bases.

ATTUNE REVISION OFFSET ADAPTOR:

The ATTUNE Revision Offset Adaptors are manufactured from wrought Co-Cr-Mo alloy conforming to ASTM 1537. They consist of two components: an offset body and a lock nut. The ATTUNE Revision offset adaptors are available in three offsets: 2 mm, 4 mm, and 6 mm. The Offset Adaptors are compatible with the ATTUNE Revision CRS Femoral Components, the ATTUNE Revision Fixed Bearing Tibial Bases, and the ATTUNE Revision Stems.

Intended Use:

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 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 when necessary to provide stability where musculoligamentous supporting structures are insufficient.

The ATTUNE Revision Total Knee is designed to accommodate knee flexion to 130 degrees in those patients able to attain a high degree of knee flexion.

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.

Summary of Technologies/ Substantial Equivalence: The ATTUNE Revision Knee System has the same indications, manufacturing methods, and sterilization methods as previously cleared DePuy total knee replacement systems. The design, materials, and packaging are similar to those of the predicate devices.

Non-Clinical Testing:

The table below lists the functional testing that was conducted in compliance with FDA Guidance, *Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses: Guidance for Industry and FDA*, to verify that the implant performance is substantially equivalent to predicate devices for anticipated in-vivo loading via various constraint, contact, wear, and fatigue tests. The results demonstrated that the subject devices are substantially equivalent to the legally marketed predicate devices.

The proposed devices also meet the requirement of bacterial endotoxin testing as specified in ANSI AAMI ST-72:2011.

Fixed Bearing Tibial Base Fatigue Testing	Patellofemoral Contact Area and Contact Pressure Testing
A-P Shear Spine Fatigue Testing	Component Interlock Strength Testing: Offset Adaptor to Stem and Stem and Tibial Base
Rollback Layout for Design Verification	Component Interlock Strength Testing: Femoral Sleeve to Femoral Component
Rotation Layout for Design Verification	Component Interlock Strength Testing: Stem to Tibial Base
Tibiofemoral Constraint Testing	Component Interlock Strength Testing: Stem to Femoral Sleeve
Medialized Dome Lateral Stability Testing	Component Interlock Strength Testing: Varus/Valgus Loading of Femur and Insert
Tibiofemoral Contact Area and Contact Pressure Testing	Component Interlock Strength Testing: Insert Insertion and Extraction

Clinical Testing: Clinical testing was not necessary to determine substantial equivalence between the ATTUNE Revision Knee System and the predicate devices.