DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 15, 2017

DePuy (Ireland)
Nancy Friddle
Associate Director, Regulatory Affairs
DePuy Orthopaedics, Inc.
700 Orthopaedic Dr.
Warsaw, Indiana 46582

Re: K170806
Trade/Device Name: ATTUNE Cemented Tibial Base, Fixed Bearing
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, OIY
Dated: March 16, 2017
Received: March 17, 2017

Dear Nancy Friddle:

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,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170806

Device Name
ATTUNE Cemented Tibial Base, Fixed Bearing

Indications for Use *(Describe)*
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.

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.

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510(k) Summary
(As required by 21 CFR 807.92 and 21 CFR 807.93)

Submitter Information	
Name	DePuy Orthopaedics, Inc.
Address	700 Orthopaedic Drive Warsaw, IN 46582
Phone number	(574) 371-4923
Fax number	(574) 371-4987
Establishment Registration Number	1818910
Name of contact person	Nancy Friddle
Date prepared	March 16, 2016
Name of device	
Trade or proprietary name	ATTUNE Cemented Tibial Base, Fixed Bearing
Common or usual name	Total Knee Prosthesis
Classification name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3560
Product Code(s)	OIY, JWH
Legally marketed device(s) to which equivalence is claimed	Primary Predicate: K101433: DePuy ATTUNE Knee System Reference Predicate: K032151: Sigma Co-Cr Tibial Trays
Reason for 510(k) submission	Addition of a new Cemented Tibial Base component to the ATTUNE Knee System
Device description	The ATTUNE Cemented Tibial Base, Fixed Bearing (FB) are available in sizes 1-10. The fixation surface incorporates a stem and keel to provide additional stability as well as recessed undercut cement pockets and a grit blasted surface for enhanced cement fixation. The tibial base utilizes a central universal locking mechanism to capture the tibial insert. The ATTUNE Cemented Tibial Base, FB is manufactured from cast Co-Cr-Mo alloy conforming to ASTM F75. Additionally, the ATTUNE Cemented Tibial Base, FB utilizes a previously cleared Base Protector assembled with the device to minimize potential marring of the proximal bearing surface of the tibial base during impaction. After impaction is completed, the Base Protector is then removed and discarded prior to inserting the ATTUNE Fixed Bearing Insert. The ATTUNE CR Total Knee is designed to accommodate knee flexion to 150 degrees in those patients able to attain a high degree of knee flexion.

	The ATTUNE PS Total Knee is designed to accommodate knee flexion to 145 degrees in those patients able to attain a high degree of knee flexion.
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 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.

Summary of Technologies/ Substantial Equivalence Discussion:	
The ATTUNE Cemented Tibial Base, FB provides a macro geometric feature and an optimized micro-blast finish which are both intended to aid in fixation of the tibial implant to the bone cement. The ATTUNE Cemented Tibial Base, FB is designed to enhance fixation by improving resistance (relative to the industry) to intra-operative factors which can result in a reduction in cement to implant bond. The subject ATTUNE Cemented Tibial Base, FB has the same indications, intended used, materials, biocompatibility, packaging configurations, manufacturing methods, and sterilization methods as the previously cleared ATTUNE Cemented Tibial Base (K101433). The subject ATTUNE Cemented Tibial Base, FB is manufactured with undercut cement pockets similar to those previously cleared with the Sigma Co-Cr Trays (K032151). The testing provided below was used to support equivalence to the predicate devices.	
Non-Clinical Testing:	Functional testing 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 the following tests: • Fatigue Testing per ASTM F 1800, Standard Practice for Cyclic Testing of Metal Tibial Tray Components of Total

	Knee Joint Replacements • Intraoperative ROM simulation and pull-off testing with lipid and marrow • Surgeon validation The proposed devices also meet the requirement of • Bacterial endotoxin testing as specified in ANSI AAMI ST-72:2011.
Clinical Testing:	Clinical testing was not necessary to determine substantial equivalence between the ATTUNE Cemented Tibial Base, FB and the predicate devices.
Conclusions drawn from non-clinical and clinical data	The subject Fixed Bearing ATTUNE Cemented Tibial Base, FB is substantially equivalent to the predicate Fixed Bearing ATTUNE Total Knee System Tibial Bases and Sigma Co-Cr Tibial Trays.