DePuy Ireland UC
% Melissa Cook
Regulatory Affairs Specialist III
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582

September 11, 2020

Re: K200854
Trade/Device Name: DePuy PINNACLE Dual Mobility Liner
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, MEH
Dated: August 10, 2020
Received: August 12, 2020

Dear Melissa Cook:

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 Vesa Vuniqi
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K200854

Device Name

DePuy PINNACLE Dual Mobility Liner

Indications for Use *(Describe)*

Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint (typically due to non inflammatory degenerative joint disease).
2. Failed previous hip surgery.
3. Dislocation risks.

PINNACLE Dual Mobility Metal Liners and Porous-coated PINNACLE Acetabular Cups are intended for 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.

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510(K) SUMMARY

(As required by 21 CFR 807.92)

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork, Ireland
Phone number	574-453-7014
Establishment Registration Number	3015516266
Name of contact person	Melissa Cook
Date prepared	March 27, 2020
Name of device	
Trade or proprietary name	DePuy PINNACLE Dual Mobility Liner
Common or usual name	Total hip joint replacement prosthesis
Classification name	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3358, 888.3353
Product Code(s)	LPH, LZO, MEH
Legally marketed device(s) to which equivalence is claimed	Stryker Modular Dual Mobility (MDM) Liner (K103233, cleared February 3, 2011) Reference device: BI-MENTUM Dual Mobility System (K181744, cleared December 11, 2018)
Reason for 510(k) submission	The subject devices are an addition to the DePuy PINNACLE Acetabular implant portfolio, to provide a dual mobility construct for total hip arthroplasty.
Device description	The DePuy PINNACLE Dual Mobility Liner is manufactured from cobalt-chrome-molybdenum alloy. The Liner is assembled with a taper locking mechanism to PINNACLE Acetabular Shells. The inner surface of the Dual Mobility Metal Liner articulates with a BI-MENTUM polyethylene mobile

	bearing head. The Dual Mobility construct is compatible with DePuy metal or ceramic modular femoral heads, for use in total hip arthroplasty.
Intended Use	The PINNACLE Dual Mobility Metal Liners are designed to provide additional stability where there is an unstable joint and are for use in total hip arthroplasty which is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. The PINNACLE Dual Mobility Metal Liners are intended for single use only.
Indications for use	**Total hip replacement or hip arthroplasty is indicated in the following conditions:** 1. A severely painful and/or disabled joint (typically due to non inflammatory degenerative joint disease). 2. Failed previous hip surgery. 3. Dislocation risks. PINNACLE Dual Mobility Metal Liners and Porous-coated PINNACLE Acetabular Cups are intended for cementless applications.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE			
Characteristics	**Subject Device: DePuy PINNACLE Dual Mobility Insert**	**Predicate Device: Stryker Modular Dual Mobility Metal Liner (K103233)**	**Reference Device: BI-MENTUM Dual Mobility System (K181744)**
Intended Use	The PINNACLE Dual Mobility Metal Liners are designed to provide additional stability where there is an unstable joint and are for use in total hip arthroplasty which is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. The PINNACLE Dual Mobility Metal Liners are intended for single use only.	Total hip arthroplasty	Total hip replacement
Liner Material	Cobalt-chrome-molybdenum alloy liner	Cobalt-chrome-molybdenum alloy liner	N/A – Device does not incorporate a modular liner
Design	Modular dual articulation	Modular dual articulation	Monoblock dual articulation

Compatible Acetabular Shells	Porous Ti6Al4V Shells, sizes 48mm – 72mm	Porous Ti6Al4V Shells, sizes 44mm – 80mm	Stainless steel Shells with commercially pure titanium and hydroxyapatite coating, sizes 41mm – 69mm
Compatible Mobile Bearing Heads	UHMWPE mobile bearing heads, 22.2mm and 28mm IDs	UHMWPE mobile bearing heads, 22.2mm and 28mm IDs	UHMWPE mobile bearing heads, 22.2mm and 28mm IDs
Sterile Method	Gamma	Gamma	Gamma
Packaging	Double PETG blister with Tyvek peel lid	Double PETG blister with Tyvek peel lid	Shells: Double PETG blister with Tyvek peel lid Mobile bearing heads: Vacuum-packed in bags and sealed in blister packaging
Shelf Life	10 years	5 years	5 years
The subject PINNACLE Dual Mobility Metal Liner has the same intended use, design, and material as the predicate Stryker Modular Dual Mobility Metal Liner (K103233). The subject device is intended for total hip arthroplasty; is a modular dual articulation construct; is made of cobalt-chromium-molybdenum alloy; and is available in the same size range as the predicate device. The subject PINNACLE Dual Mobility Metal Liner has the same intended use and is compatible with the same UHMWPE Mobile Bearing Heads as the reference device BI-MENTUM Dual Mobility System (K181744).			

PERFORMANCE DATA

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

The following tests were performed on the PINNACLE Dual Mobility Metal Liner to demonstrate substantial equivalence of safety and efficacy with the predicate devices:

- Range of motion in accordance with ISO 21535:2007 / AMD 2016
- Verification of product compatibility
- Standard walking wear testing
- Jump distance assessment
- Mechanical testing in partial compliance with ASTM F1820
- Taper performance testing
- The proposed devices also meet the requirement of bacterial endotoxin testing as specified in ANSI/AAMI ST72:2011

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 PINNACLE Dual Mobility Metal Liners are substantially equivalent to the predicate Stryker Modular Dual Mobility Metal Liner.