November 26, 2019

DePuy Orthopaedics, Inc.
% Margaret Shaughnessy
Regulatory Affairs Project Leader
DePuy (Ireland)
Loughbeg, Ringakiddy
CORK P43D82
IRELAND

Re: K192919
Trade/Device Name: Pinnacle Duofix HA Acetabular Cup Prosthesis
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
Dated: October 11, 2019
Received: October 15, 2019

Dear Margaret Shaughnessy:

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)*

K192919

Device Name
DePuy Pinnacle Duofix™ HA Acetabular Cups

Indications for Use *(Describe)*

The Pinnacle Duofix™ HA Acetabular Cup Prosthesis is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for revision of the previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Duofix HA Acetabular Cup Prosthesis is indicated for cementless application.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

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

Submitter Information	
Name	DePuy Orthopaedics
Address	700 Orthopedic Drive Warsaw, IN 46582
Phone number	574 372 7020
Fax number	574- 371-4987
Establishment Registration Number	1818910
Name of contact person	Kathy Harris
Date prepared	
Name of device	
Trade or proprietary name	Pinnacle Duofix™ HA Acetabular Cup Prosthesis
Common or usual name	Acetabular Cup Prosthesis
Classification name	Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis
Class	II
Classification panel	87 Orthopedic and Rehabilitation Devices
Regulation	888.3358
Product Code(s)	LPH
Legally marketed device(s) to which equivalence is claimed	Pinnacle Duofix™ HA Acetabular Cup Prosthesis – K000306, K031495
Reason for 510(k) submission	The purpose of this submission is to support the manufacturing of the subject Pinnacle Duofix™ HA Acetabular Cup Prosthesis System components at an additional manufacturing facility for all process steps at DePuy Ireland. This includes the HA coating process step within the DePuy Ireland manufacturing site. There is also the addition of two alternative sterilization sites being added for Business Continuity Purposes. There is a modification to the packaging process too. We are converting from a double pouch packaging system to a double blister packaging system as per the original submission K000306 There are no other modifications associated with this product in comparison with the currently marketed Pinnacle Duofix™ HA Acetabular Cup Prosthesis – the predicate and proposed device share the same intended use, product design, principle of operation, and materials.
Device description	The Pinnacle Duofix HA Acetabular Cup Prosthesis is a sintered, porous-coated (Porocoat®) hemispherical outer acetabular shell manufactured from titanium alloy (Ti-6Al-4V) with a thin layer of hydroxyapatite (HA) coating applied. The interior of the acetabular cup is designed with a groove and a taper for use with either an ultra-high molecular weight polyethylene (UHMWPE) or metal

	acetabular cup liner, which lock into the shell. Articulation occurs between the liner, and a femoral head with the appropriately sized diameter. The shells contain an apical threaded hole to allow the surgeon to attach the shell insertion instrument and grasp the shell during implantation. An optional titanium alloy (Ti-6Al-4V) apical hole plug is available to screw into the threaded apical hole of the shell. The plug is intended to occlude the apical hole in order to prevent particulate migration and provide polyethylene support. The Pinnacle Duofix HA Acetabular Cup Prosthesis is provided in shell diameter sizes 48mm through 66mm in both the "No Hole" (100 series) and the "Cluster Hole" (Sector series) configurations.
Intended use of the device	The Pinnacle Duofix HA Acetabular Cup Prosthesis is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for revision of the previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques. The Pinnacle Duofix HA Acetabular Cup Prosthesis is indicated for cementless application.
Indications for use	The Pinnacle Duofix™ HA Acetabular Cup Prosthesis is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for revision of the previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques. The Pinnacle Duofix HA Acetabular Cup Prosthesis is indicated for cementless application.

Characteristics	**Subject Device:** Pinnacle Duofix™ HA Acetabular Cup Prosthesis	**Predicate Device:** Pinnacle Duofix™ HA Acetabular Cup Prosthesis – K031495	**Predicate Device:** Pinnacle Duofix™ HA Acetabular Cup Prosthesis – K000306
Intended Use	The Pinnacle Duofix™ HA Acetabular Cup Prosthesis is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for revision of the previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.	Same	Same
Material	**Acetabular Shell**: Forged Titanium alloy (Ti-6A1-4V) conforms to ASTM F-620 **Porous Coating**: Commercially pure unalloyed (ASTM F67) titanium sintered bead porous coating (Porocoat®) **HA Coating**: the HA powder used in a plasma spray process, conforms to ASTM F1185 Hydroxyapatite ($Ca_5(PO_4)_3OH$) ceramic.	Same	**Acetabular Shell**: Wrought titanium alloy (Ti-6Al-4V) conforms to ASTM F-136 or forged titanium alloy (Ti-6A1-4V) conforms to ASTM F-620 **Porous Coating**: Commercially pure unalloyed (ASTM F67) titanium sintered bead porous coating (Porocoat®)
Fixation	Cementless	Same	Same
Cup Size	Pinnacle Cup 100 Series 48, 50, 52, 54, 56, 58, 60, 62, 64, 66 Pinnacle Cup Sector Series 48, 50, 52, 54, 56, 58, 60, 62, 64, 66	Same	Same

Characteristics	Subject Device: Pinnacle Duofix™ HA Acetabular Cup Prosthesis	Predicate Device: Pinnacle Duofix™ HA Acetabular Cup Prosthesis – K031495	Predicate Device: Pinnacle Duofix™ HA Acetabular Cup Prosthesis – K000306
Sterile Method	Sterilization method and dose: Cobalt-60-Gamma radiation (25-40kGy)	Same	Same
Packaging	Double blister packaging consisting of inner and outer trays of Polyethylene Terephthalate Glycol copolymer (PETG) with lids of TYVEK®.	Double peel pouch packaging consisting of an inner and an outer vacuum sealed pouch of Nylon polymer	Same
Shelf Life	10 Year	Same	Same

PERFORMANCE DATA

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

The following tests were performed on the Pinnacle Cup to demonstrate substantial equivalence of safety and efficacy with the predicate devices:

- Biological safety per ISO 10993-1 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing".
- Sterilization validation per AAMI ANSI ISO 11137-1: 2006/(R)2010 and AAMI ANSI ISO 11137-2: 2013
- Characterization testing of Hydroxyapatite Coating as recommended per FDA Guidance: "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implant"

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 DePuy Pinnacle Cup products are substantially equivalent to the predicate Pinnacle Cup products (K00306, K031495)