DePuy Orthopaedics Inc.
% Ann Geraghty
Regulatory Affairs Acting Project Leader
DePuy Ireland
Loughbeg Ringaskiddy
Cork, Co. Cork P43ED82
Ireland

October 21, 2020

Re: K202472
Trade/Device Name: ACTIS Duofix Hip 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, MEH, KWL, KWY
Dated: September 17, 2020
Received: September 22, 2020

Dear Ann Geraghty:

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,

Vesa Vuniqi, M.S.
Assistant Director
DHTA: Division of Joints Arthroplasty
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202472

Device Name

ACTIS Duofix Hip Prosthesis

Indications for Use *(Describe)*

Total hip replacement or hip arthroplasty is indicated in the following conditions:
1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Certain cases of ankylosis.

Partial hip replacement or hip hemi-arthroplasty is indicated in the following conditions:
1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation.
2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation.
3. Avascular necrosis of the femoral head.
4. Non-union of femoral neck fractures.
5. Certain high subcapital and femoral neck fractures in the elderly.
6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement.
7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hip hemi-arthroplasty.

The ACTIS™ DUOFIX™ Hip Prosthesis is indicated for cementless use only.

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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6. 510(k) Summary

6.1. 510(k) Summary

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

Submitter Information	
Name	DePuy Ireland
Address	Loughbeg, Ringaskiddy, Co. Cork, Ireland
Phone number	+353-21-4914857
Fax number	574- 371-4987
Establishment Registration Number	1818910
Name of contact person	Ann Geraghty
Date prepared	21st October 2020
Name of device	
Trade or proprietary name	ACTIS Duofix™ Hip Prosthesis
Common or usual name	Uncemented Hip Prosthesis
Classification name	MEH - Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis LPH - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis KWL - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis KWY - Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Class	II
Classification panel	87 Orthopedic
Regulation	21 CFR 888.3358, 888.3353, 888.3360, 888.3390
Product Code(s)	LPH, MEH, KWL, KWY
Legally marketed device(s) to which equivalence is claimed	**Primary Predicate:** DePuy ACTIS Duofix™ Hip Prosthesis K150862 (sizes 1-12) cleared September 25, 2015 **Additional Predicates:** DePuy ACTIS Duofix™ Hip Prosthesis K160907 (size 0) cleared July 19th, 2016 DePuy SUMMIT Duofix™ Hip Prosthesis K193398, cleared February 4, 2020
Reason for 510(k) submission	The purpose of this submission is to support the change to add DePuy Ireland as an alternate manufacturing facility for the HA coating process step and to add DePuy Orthopaedics Inc. Warsaw IN as an

	alternate site for grit-blasting the device prior to coating. The remaining manufacturing process steps will continue to be performed at the existing locations. There are no other modifications to the product associated with these changes in comparison with the currently marketed ACTIS Hip System – the predicate and proposed device share the same intended use, product design, principle of operation, and materials.
Device description	The ACTIS Duofix™ Hip Prosthesis is identical to the previously cleared ACTIS Duofix™ Hip Prosthesis (K150862 & K160907). The ACTIS Duofix™ Hip prostheses are manufactured from forged titanium alloy (Ti6Al4V), have a sintered commercially pure titanium bead porous coating (Porocoat ®), and thin layer of plasma-sprayed hydroxyapatite (HA) coating. The stem consists of a wide range of stem neck designs and sizes allowing an anatomical match for each patient. The stems are compatible with both unipolar and bipolar heads intended for hip hemi-athroplasty and with modular metal or ceramic femoral heads intended for total hip arthroplasty. The porous coating is applied over the proximal region of the stem. A thin coating of hydroxyapatite (HA) of uniform thickness is sprayed over the porous and distal stem areas via a plasma spray process. The HA powder used in the plasma spray process conforms to ASTM F1185-88 and ISO 13779-6 Hydroxyapatite ($Ca_5(PO_4)_3OH$) ceramic. The plasma spray process used to apply the HA coating to the ACTIS Duofix™ Stem is the same process used to coat the SUMMIT Duofix™ Stem which was cleared in K193398. The HA material used for the ACTIS Duofix™ Stem is the same as the HA material used on the SUMMIT Duofix™ Stem. Thirteen sizes of prostheses are provided to allow high resolution of fit within host femora. Each size is offered in standard and high offset neck options, desired recreation of patient biomechanics in combination with head and liner combinations.
Intended use of the device	The ACTIS Duofix™ Hip Prosthesis is intended for use in total hip arthroplasty 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 ACTIS Duofix™ Hip Prosthesis is intended for use in hemi-hip arthroplasty where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral stem.

Indications for use	***Total hip replacement or hip arthroplasty is indicated in the following conditions***: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia. 2. Avascular necrosis of the femoral head. 3. Acute traumatic fracture of the femoral head or neck. 4. Certain cases of ankylosis. ***Hemi hip replacement is indicated in the following conditions***: 1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation. 2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation. 3. Avascular necrosis of the femoral head. 4. Non-union of femoral neck fractures. 5. Certain high subcapital and femoral neck fractures in the elderly. 6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement. 7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty. The ACTIS Duofix™ Hip Prosthesis is indicated for cementless use only.

PERFORMANCE DATA
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE
The following tests were performed on the ACTIS Hip 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". • Characterization testing of Hydroxyapatite Coating as recommended per FDA Guidance: "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implant" – Performance Bench Testing - Body (Distal) Fatigue Testing per ISO 7206-4 2010.
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
No clinical tests were necessary to clear the current device and thus no clinical testing was conducted here to demonstrate substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The subject DePuy ACTIS Duofix™ Hip products are substantially equivalent to the predicate ACTIS and Summit Hip products (K150862, K160907 and K193398)