DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 19, 2016

DePuy (Ireland)
% Ms. Correne Ramy
Project Leader, Regulatory Affairs
Depuy Orthopaedics, Incorporated
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K160907
Trade/Device Name: DePuy Actis DuoFix Hip Prosthesis
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH, LPH, KWL, KWY
Dated: June 10, 2016
Received: June 13, 2016

Dear Ms. Ramy:

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 Parts 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" (21CFR 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

Section 4: Indications for Use Statement

510 (k) Number (if known): K160907

Device Name: DePuy Actis DuoFix Hip Prosthesis

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.

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 DePuy Actis DuoFix Hip Prosthesis is indicated for cementless use only.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

K160907

Section 5: 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	574-371-4981
Fax number	574- 371-4987
Establishment Registration Number	1818910
Name of contact person	Correne Ramy
Date prepared	March 31, 2016
Name of device	
Trade or proprietary name	DePuy Actis DuoFix Hip Prosthesis
Common or usual name	MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calicum-phosphate LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented KWL - prosthesis, hip, hemi-, femoral, metal KWY - prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented
Classification name	MEH - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous 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 Orthopedics
Regulation	21 CFR 888.3353, 888.3358, 888.3360, 888.3390
Product Code(s)	MEH, LPH, KWL, KWY
Legally marketed device(s) to which equivalence is claimed	DePuy Actis DuoFix Hip Prosthesis (K150862, cleared September 25, 2015)
Reason for 510(k) submission	Line extension of an additional smaller size hip stem
Device description	The DePuy Actis DuoFix Hip prostheses are manufactured from forged

	titanium alloy (Ti6Al4V) and 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 accurate anatomical match for each patient. The stems are compatible with both unipolar and bipolar heads intended for hemi-arthroplasty and with modular metal and ceramic femoral heads intended for total hip arthroplasty.
Intended use of the device	Total hip arthroplasty and hemi-hip arthroplasty
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. **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 DePuy Actis DuoFix Hip Prosthesis is indicated for cementless use only.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristics	**Subject Device:** **DePuy Actis DuoFix Hip Prosthesis**	**Predicate Device:** **DePuy Actis DuoFix Hip Prosthesis (K150862)**
Intended Use	Total Hip Arthroplasty, Hemi-Hip Arthroplasty	Same
Material	Ti6AL4V with Porocoat and plasma sprayed HA coating	Same
Fixation	Uncemented	Same
Stem Size	0	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
Neck Offset	Standard, High	Same
Collar	Collared	Same
Sterile Method	Gamma	Same
Packaging	Inner nylon pouch and outer PETG blister with Tyvek peel lid	Same
Shelf Life	10 years	Same
PERFORMANCE DATA		
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE		
Neck fatigue testing in accordance with ISO 7206-6:2013 Distal fatigue testing in accordance with ISO 7206-4:2010 Pyrogenicity testing using the Bacterial Endotoxin Testing (BET) method as specified in ANSI/AAMI ST-72:2011		
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 devices are substantially equivalent to the predicate DePuy Actis DuoFix Hip Prosthesis.