

Section 5: 510 (k) Summary

As required by 21 CFR 807.92(c)

Sponsor	
Name	DePuy Orthopaedics France S.A.S.
Address	7 Allee Irene Joliot Curie bp256; Saint Priest Cedex, France 69801
Phone number	+33 4 72 79 27 27
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Establishment Registration Number	3003895575
Application Correspondent	
Name	DePuy Orthopaedics, Inc.
Address	700 Orthopaedic Drive Warsaw, IN 46581
Phone number	(574)-372-7349
Fax number	(574) 371-4987
Establishment Registration Number	1818910
Name of contact person	Alma Relja, RAC
Date prepared	December 19, 2012
Name of device	
Trade or proprietary name	Corail AMT™ Hip Prosthesis
Common or usual name	Hip Stem
Classification name	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; Class II Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis; Class II
Classification panel	87 - Orthopedics Branch, Division of General and Restorative Devices
Regulation	21 CFR 888.3390; 888.3353; 888.3360
Product Code(s)	KWY, LZO, KWL
Legally marketed device(s) to which equivalence is claimed	Corail AMT™ Hip Prosthesis (K070554; K042992) MetaFix Femoral Stem for Hemi-Arthroplasty (K120362) Apex ARC Hip Stem (K113242; K111193)
Reason for 510(k) submission	Expand currently cleared Indication for Use to add hip hemi-arthroplasty surgical application

SEP 16 2013

Device description	The Corail AMT Hip is a tapered stem available both collarless and collared. The stems are manufactured from titanium alloy (Ti6Al4V) and plasma-sprayed with a biocompatible hydroxyapatite (HA) coating for bone fixation. The Corail AMT stems feature a 12/14 modular taper that accepts 12/14 heads with a wide range of diameters. The compatible components for the hip hemi-arthroplasty application are bipolar heads cleared via 510(k) K812672 and unipolar heads cleared via 510(k) K903084. Corail AMT stems are indicated for cementless use only.
Intended Use	Total Hip Arthroplasty and Hemi Hip Arthroplasty
Indications for Use	<p>Total hip replacement or hip arthroplasty is indicated in the following conditions:</p> <ol style="list-style-type: none"> 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. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemi-arthroplasty, surface replacement arthroplasty, or total hip replacement. 5. Certain cases of ankylosis. <p>Partial hip replacement or hip hemi-arthroplasty is indicated in the following conditions:</p> <ol style="list-style-type: none"> 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. <p>HA coated stems of the Corail Hip System are indicated for cementless use only.</p>

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	DePuy Orthopaedics Corail AMT™ Hip Prosthesis (subject device, predicate devices: K070554; K042992)	MetaFix Femoral Stem for Hemi-Arthroplasty (K120362)	Apex ARC Hip Stem (K113242 and K11193)
Material	Ti-6Al-4V	Same as Subject Device	Same as Subject Device
Stem Surface	plasma-sprayed with a biocompatible hydroxyapatite (HA) coating for bone fixation	Same as Subject Device	Same as Subject Device
Compatible Femoral Heads	Bipolar and Unipolar	Same as Subject Device	Bipolar
Taper Design	12/14 taper	Same as Subject Device	Same as Subject Device
Placement	Press Fit; Cementless	Same as Subject Device	Same as Subject Device

PERFORMANCE DATA

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

The following non-clinical performance data is provided in this submission:

- Validation of the taper/heads - dimensional compatibility with Corail AMT Stems
- Fatigue Resistance tests for the Corail AMT Stems

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

No clinical tests have been performed for determination of substantial equivalence.

However, included in this submission is a clinical evaluation utilizing systematic literature review of Corail Hip System for the treatment of femoral neck fractures. This clinical evaluation of the subject device is based on an assessment of the risks and benefits associated with the use of the device through a systematic compilation of the relevant scientific literature currently available and a critical evaluation of the clinical literature identified.

The fundamental scientific technology of the Corail AMT Hip stem has not changed in order to expand the indications for use to add hip hemi-arthroplasty and utilize the compatible unipolar and bipolar heads. The safety and effectiveness of the subject Corail AMT Hip stem is adequately supported by the substantial equivalence information, materials information, review of clinical literature to support the modified indications for use and performance test data provided in this submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 16, 2013

DePuy France S.A.S
% Ms. Alma Relja
DePuy Orthopaedics, Incorporated
700 Orthopaedic Drive
Warsaw, Indiana 46581

Re: K123991

Trade/Device Name: Corail AMT™ Hip Prosthesis

Regulation Number: 21 CFR 888.3390

Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis

Regulatory Class: Class II

Product Code: KWY, LZO, KWL

Dated: August 14, 2013

Received: August 15, 2013

Dear Ms. Relja:

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

Page 2 – Ms. Alma Relja

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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): K123991 (pg 1/1)

Device Name: Corail AMT Hip Prosthesis

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. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. 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.

HA coated stems of the Corail Hip System are 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.)

Concurrence of Center for Devices and Radiological Health

Elizabeth L. Frank -S

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