SUMMARY OF SAFETY AND EFFECTIVENESS

SEP 11 2007

NAME OF FIRM: DePuy France S.A.
7 Allee Irene Joliot Curie
69801 Saint Priest cedex
France
Establishment Registration Number: 9007981

510(K) CONTACT: Kathy Harris
Director, Regulatory Affairs
Tel: (574) 372-7082
Fax: (574) 371-4987

TRADE NAME: DePuy Corail AMT™ Hip Prosthesis

COMMON NAME: Hip Stem

CLASSIFICATION: 21 CFR 888.3330: Hip joint metal / metal semi-constrained prosthesis, with an uncemented acetabular component; Class III
21 CFR 888.3353: Hip joint metal / ceramic / polymer semi-constrained cemented or nonporous uncemented prosthesis; Class II

DEVICE PRODUCT CODES: LZO, MEH, KWA

SUBSTANTIALLY EQUIVALENT DEVICES: DePuy Corail AMT Hip Prosthesis (K042992)
DePuy S-Rom Femoral Hip Stem, Size 12 x 06 x 115 (K961939)

DEVICE DESCRIPTION:
The Corail AMT Hip Prosthesis is a collarless, hydroxyapatite coated titanium alloy femoral stem. The Corail AMT Hip Prosthesis is similar to the previously cleared Corail AMT Hip Prostheses but has a shorter stem length, shorter neck length and smaller cross-section. The Corail AMT Hip Prostheses is contraindicated in patients weighing more than 84 lbs.

INDICATIONS FOR USE:
The Corail AMT Hip Prosthesis is intended for use in total hip arthroplasty and is intended for press fit (uncemented) use. Total hip arthroplasty 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. Total hip replacement 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.

The non-porous Corail AMT Hip Stem is indicated for cementless use only.

BASIS FOR SUBSTANTIAL EQUIVALENCE:
The Corail AMT Hip Prosthesis is a modification of the Corail AMT Hip Prostheses that were cleared in K042992. Based on similarities in indications, intended use, design, materials, method of manufacture and the results of fatigue testing, DePuy believes that the Corail AMT Hip Prosthesis is substantially equivalent to the previously cleared Corail AMT Hip Prostheses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Kathy Harris
Director, Regulatory Affairs
P.O. Box 988
Warsaw, Indiana 46581-0988

SEP 11 2007

Re: K070554
Trade/Device Name: Corail AMT Hip Prosthesis
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, LZO, MEH
Dated: August 13, 2007
Received: August 16, 2007

Dear Ms. Harris:

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.

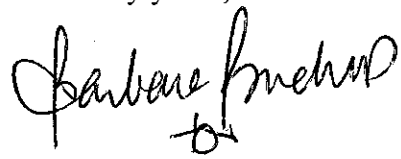
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K070554

Device Name: DePuy Corail AMT Hip Prosthesis

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K070554