K102423
PG. 1/2

510(k) Summary

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

OCT 29 2010

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Brandon Hipsher, MBA RAC Manager, Regulatory Affairs Telephone: (574) 372-7465 Facsimile: (574) 371-4987 Electronic Mail: bhipsher@its.jnj.com
DATE PREPARED:	September 21, 2010
PROPRIETARY NAME:	DePuy Pinnacle® AltrX™ Acetabular Liners
COMMON NAME:	Polyethylene Acetabular Cup Liner
CLASSIFICATION AND REGULATION:	Class II per 21 CFR 888.3358: Hip joint metal/polymer/metal, semi-constrained, porous-coated, uncemented prosthesis (**LPH**) Class II per 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis (**LZO**)
DEVICE PRODUCT CODE AND DESCRIPTION:	**LPH**: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented **LZO**: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
PREDICATE DEVICES	DePuy Pinnacle AltrX Acetabular Liners (K072963, cleared January 9, 2008)

DEVICE DESCRIPTION:

The DePuy Pinnacle AltrX Acetabular Liners are part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The liner is manufactured from ultra high molecular weight polyethylene (UHMWPE), which locks into a porous coated, hemispherical outer shell component manufactured from titanium alloy (Ti-6Al-4V). The liner component articulates with a metal or ceramic femoral head of an appropriate diameter. The subject devices represent four additional sizes of the predicate acetabular liners.

INDICATIONS AND INTENDED USE:

Indications:
The DePuy Pinnacle AltrX Acetabular Cup Liners are indicated for use in total hip replacement procedures.

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 Pinnacle AltrX Acetabular Cup Liners are indicated for use with Pinnacle Acetabular Cups in cementless applications.

Intended Use:
The subject liners are intended to be used with the DePuy Pinnacle metal acetabular shells and DePuy metal or ceramic femoral heads to resurface the acetabular socket in cementless total hip arthroplasty. 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 support the components.

Summary of Technologies/Substantial Equivalence:
The substantial equivalence of the subject DePuy Pinnacle AltrX Acetabular Liners is demonstrated by the similarities in intended use, indications for use, design, materials and performance as compared to the predicate device. The additional sizes do not present new issues of safety or effectiveness.

Nonclinical Testing:
Nonclinical testing was provided, including push-out, torque, impingement and high angle fatigue testing. This testing and an evaluation of the device design and geometry demonstrated that the subject devices met the applicable performance requirements and are as safe and effective as the predicate.

Clinical Testing:
No clinical testing was required to demonstrate substantial equivalence.

Conclusion:
The subject DePuy Pinnacle AltrX Acetabular Liners are substantially equivalent to the predicate device identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DePuy Orthopaedics, Inc.
% Brandon Hipsher, MBA RAC
Manager, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46582

OCT 29 2010

Re: K102423
Trade/Device Name: DePuy Pinnacle AltrX Acetabular Liners
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prothesis
Regulatory Class: II
Product Code: LPH, LZO
Dated: September 28, 2010
Received: September 29, 2010

Dear Mr. Hipsher:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

OCT 2 9 2010

510 (k) Number (if known): K102423

Device Name: DePuy Pinnacle AltrX Acetabular Liners

Indications for Use:

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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.)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102423