K072963 # 1/3

510 (k) Summary

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

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Rhonda Myer Regulatory Affairs Associate Telephone: (574) 371-4927 Facsimile: (574) 371-4987 Electronic Mail: Rmyer7@dpyus.jnj.com
DATE PREPARED:	October 9, 2007
PROPRIETARY NAME:	DePuy Pinnacle® AltrX™ Acetabular Liners
COMMON NAME:	Polyethylene Acetabular Cup Liner
CLASSIFICATION:	Class II per 21 CFR 888.3358, Hip joint metal/polymer/metal, semi-constrained, porous-coated, uncemented prosthesis Class II per 21 CFR 888.3353, Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis
DEVICE PRODUCT CODE:	87 LPH, LZO
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy Pinnacle® AltrX™ Acetabular Liners, K062148, October 24, 2006

DEVICE DESCRIPTION:

The DePuy Pinnacle AltrX Acetabular Liner is 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-6A1-4V). The liner component articulates with a metal or ceramic femoral head of an appropriate diameter.

The subject Pinnacle AltrX liners are cross-linked UHMWPE acetabular cup liners that are available in a neutral, lateralized neutral, lipped or lateralized face-changing orientation. The

subject liners are intended for use with modular, unipolar, self-centering (bipolar), M-Spec or ceramic femoral heads within the 28mm-48mm size range.

The following marketing claim will be made for the Pinnacle Altrx liner:

Pinnacle AltrX UHMWPE liners (articulated against ceramic heads) reduce wear by 33% compared to articulation against cobalt-chromium heads.

An in-vitro hip simulator wear study was conducted to support these wear claims. The study was conducted using test devices identified as AltrX Polyethylene Liners and control devices identified as AltrX or Enduron™ Polyethylene Acetabular Cup Liners (inner diameter of 28 mm or 36 mm) used with DePuy cobalt chromium or Delta™ Ceramic Femoral Heads. The control devices are manufactured by DePuy Orthopaedics, Inc. of ram-extruded bars and machined into Pinnacle liners. The test devices are manufactured by DePuy Orthopaedics, Inc. of ram-extruded bars, irradiated to 7.5 Mrad in vacuum, remelted and machined into Pinnacle liners. The subject liners were not terminally sterilized prior to testing.

Test and control liners were tested for 5 million cycles using a 12-station orbital bearing hip simulator manufactured by Shore Western Manufacturing Inc. The thickness of the test liner was 5.53 mm. The heads were roughened after 5 million cycles by tumbling for 30 minutes with a bauxite/alumina abrasive media in a tabletop tumbler made by A.E. Aubin Co. and tested for an additional 2 million cycles against the liners. The articulating components for the test and control liners include 28 mm and 36 mm CoCrMo femoral heads, and 36 mm ceramic femoral heads. The lubricant used in the study was 90% bovine serum with 0.2% NaN_3 and 20mM EDTA. The wear rates determined at the conclusion of the study were 34.3 ± .51 mg/million cycles (mg/MC) for the 28 mm CoCrMo femoral head/Enduron group (control), 31.54 ± 0.8 mg/MC for the 36 mm CoCrMo femoral head/Enduron group (control), 4.99 ± 0.66 mg/MC for the 36 mm CoCrMo femoral head/AltrX (control), and 3.32 ± 0.38 mg/MC for the 36 mm ceramic femoral head/AltrX test group.

Note: Reduced Wear Claims are based on the results of in-vitro hip wear simulator tests which have not been shown to quantitatively predict clinical wear performance

INDICATIONS AND INTENDED USE:

Indications:

The 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 liner is 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 seat and support the components.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Pinnacle AltrX Acetabular Liner described in this submission is identical to the DePuy Pinnacle AltrX Acetabular Liner previously cleared in K062148 on October 24, 2006. The subject liners have not been modified from the previously cleared Pinnacle AltrX liners, and based upon the referenced testing, DePuy wishes to make a claim of reduced wear when the subject liners are used with ceramic femoral heads.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2008

Depuy Orthopaedics, Inc.
% Ms. Rhonda Myer
Regulatory Affairs Associate
700 Orthopaedic Drive
Warsaw, IN 46582

Re: K072963
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 prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: January 2, 2008
Received: January 3, 2008

Dear Ms. Myer:

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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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): K072963

Device Name: DePuy Pinnacle® AltrX™ Acetabular Cup Liner

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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.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

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

510(k) Number K072963