K093646

DEC 17 2009

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 Senior Regulatory Affairs Associate Telephone: (574) 371-4927 Facsimile: (574) 371-4987 Electronic Mail: rmyer7@its.jnj.com
DATE PREPARED:	December 15, 2009
PROPRIETARY NAME:	**DePuy Pinnacle® with Gription™ Acetabular Cups**
COMMON NAME:	Acetabular Cup with Porous Coating
CLASSIFICATION:	Class III per 21 CFR 888.3330: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (KWA) Class II per 21 CFR 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis (JDI) Class II per 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (LZO) Class II per 21 CFR 888.3358: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis (LPH)
DEVICE PRODUCT CODE:	KWA, JDI, LZO, LPH
SUBSTANTIALLY EQUIVALENT DEVICE:	**Pinnacle 100 with Gription Acetabular Cups**, K090998, cleared on June 12, 2009 **Pinnacle with Gription Acetabular Cups**, K071784, cleared on July 25, 2007

DEVICE DESCRIPTION:

The Pinnacle Acetabular System is part of a modular system for use in total hip replacement. The acetabular component is provided as two separate units, a porous coated hemispherical outer shell manufactured from titanium alloy (Ti-6Al-4V) and a liner manufactured from ultra high molecular weight polyethylene (UHMWPE) or high-carbon cobalt chrome (CrCoMo), both of which lock into the outer shell. The liner component articulates with a femoral head of an appropriate diameter, which mates with a compatible DePuy femoral stem. The subject acetabular cups are coated with a proprietary titanium porous coating, Griptionᵀᴹ.

INDICATIONS AND INTENDED USE:

Indications:

The Pinnacle Acetabular Cups are indicated for total hip replacement in the following conditions:

1. A severely painful and/or a severely disabled joint resulting 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 arthoplasty, or other total hip replacement; and
5. Certain cases of ankylosis.

Porous-coated Pinnacle Acetabular Cups are indicated for cementless application.

Intended 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.

Pinnacle porous-coated Acetabular Cup total hip components are indicated for cementless use with fixation provided by biological tissue ingrowth into the porous coating.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The subject Pinnacle with Gription Acetabular Cups are identical to those cleared in K071784. The only change proposed is to add three FDA classifications to the classification cleared in K071784 (LPH) so that the classifications for all Pinnacle with Gription Cups are the same as those cleared for the Pinnacle 100 with Gription Cups in K090998 (LPH, KWA, JDI, LZO). Based on the similarities in intended use, indications for use, materials, method of manufacturing, design, sterilization and

packaging method, the subject cups are substantially equivalent to the Pinnacle 100 with Gription Acetabular Cups cleared in K090998.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DePuy Orthopaedics, Inc.
% Ms. Rhonda Myer
Senior Regulatory Affairs Associate
PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46582-0988

DEC 17 2009

Re: K093646
Trade/Device Name: DePuy Pinnacle with Gription Acetabular Cups
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular, prosthesis
Regulatory Class: Class III
Product Code: KWA, JDI, LZO, LPH
Dated: November 23, 2009
Received: November 25, 2009

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 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

Indications for Use Statement

510 (k) Number (if known): K093646

Device Name: **DePuy Pinnacle with Gription Acetabular Cups**

Indications for Use:

DePuy Pinnacle with Gription Acetabular Cups are indicated for total hip replacement in the following conditions:

1. A severely painful and/or a severely disabled joint resulting 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 other total hip replacement; and
5. Certain cases of ankylosis.

Porous-coated Pinnacle Acetabular Cups are indicated for cementless application.

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 K093646

p. 1 of 1