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MAY 19 2006

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:

DePuy Orthopaedics Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
EST REG No.: 1818910

510(K) CONTACT:

Anne Schuler
Sr Regulatory Affairs Associate
Tel: (574) 372-7098
Fax: (574) 371-4987

TRADE NAME:

DePuy Solution System® Hip Prosthesis

COMMON NAME:

Cementless or Cemented Porous Coated Hip Prosthesis

CLASSIFICATION:

21 CFR 888.3358: Hip joint metal/polymer semi-constrained porous coated uncemented prosthesis, Class II Device

DEVICE PRODUCT CODE:

87 LPH

SUBSTANTIALLY EQUIVALENT DEVICES:

DePuy Solution System® Hip Prostheses (K030979, cleared April 24, 2003)
Depuy Summit™ Cemented Hip Prosthesis (K013352, cleared December 17, 2001)
DePuy Vision Solution Hip Prosthesis (K953703, cleared February 1, 1996)

DEVICE DESCRIPTION:

The subject device, DePuy Solution System® Hip Prosthesis, is manufactured from ASTM F-799 Forged Controlled-Carbon Cobalt-Chromium-Molybdenum alloy and has a sintered cobalt-chrome molybdenum alloy bead porous coating (Porocoat®) applied to the stem. The porous coating is applied to the entire stem with the exception of the tapered stem tip region. The stems are available in 10.5, 12.0 and 13.5 mm sizes.

INTENDED USE:

The DePuy Solution System® Hip Prosthesis is intended for use in total hip arthroplasty (THA) in either a cementless or cemented application. Total hp 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.

SUBSTANTIAL EQUIVALENCE:

Based on the same intended use, indications, sterilization method, packaging and design, DePuy believes that the Solution System® Hip Prosthesis is substantially equivalent to the FDA-cleared DePuy Solution System® Hip Prosthesis (K030979), the Vision Solution Hip Prosthesis (K953703) and the Depuy Summit™ Cemented Hip Prosthesis (K013352).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2006

DePuy Orthopaedics Inc.
c/o Ms. Anne M. Schuler
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K060581
Trade/Device Name: Depuy Solution System® Hip Prosthesis
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: April 14, 2006
Received: April 19, 2006

Dear Ms. Schuler:

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 Office of Compliance at (240) 276- 1020. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for 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

510(k) Number (if known): K060581
Device Name: DePuy Solution System® Hip Prosthesis

Indications for 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 Solution System® Hip Stem is indicated for cementless use and fixation by biological tissue ingrowth into the porous coating as well as cemented use and fixation in which the porous coating serves as a means to augment the fixation of the prosthesis to the bone cement.

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

510(k) Number K060581

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)