SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:

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

AUG 2 8 2006

510(K) CONTACT:

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

DATED PREPARED: June 22, 2006

TRADE NAME: DePuy S-ROM® STD Hip Stem Prosthesis

COMMON NAME: Cementless Hip Stem Prosthesis

CLASSIFICATION:

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

21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis, Class II

21 CFR 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis, Class III

DEVICE PRODUCT CODES: LPH, LZO, KWA

SUBSTANTIALLY EQUIVALENT DEVICES:

DePuy S-ROM® Femoral Hip Stem (K961939, cleared August 13, 1996)

DePuy S-ROM® STD Hip Stem Prostheses (K851422, cleared July 9, 1985 with additional modifications cleared through internal documentation)

DEVICE DESCRIPTION:

The subject DePuy S-ROM® Hip Stem is a line extension to the 36mm S-ROM® titanium stems previously cleared in K961939 and K851422. The line extension adds a +12L option to the previously cleared standard stem sizes 19 x 24 x 175 w/36mm neck and 21 x 26 x 175 w/36mm neck. These two new stems will provide greater lateralization (+12 mm) to the standard stem of comparable diameters. The increased lateralization assists in restoring anatomical biomechanics through adjusting off-set without effecting leg length.

INTENDED USE AND INDICATIONS:

INTENDED USE:

The DePuy S-ROM® Hip Stem Prosthesis 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 component.

INDICATIONS FOR USE:

The DePuy S-ROM® Hip Stem Prosthesis is indicated for uncemented use as the femoral component in total hip arthroplasty (THA) for replacing the hip joints of patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicted for revision of previous hip arthroplasty and for patients with congenital hip dysplasia, *protrusion acetabuli*, slipped capital femoral epiphysis, and disability due to previous fusion.

SUBSTANTIAL EQUIVALENCE:

The fundamental scientific technologies of the subject DePuy S-ROM® Hip Prosthesis have not changed from the FDA-cleared DePuy S-ROM® Hip Stem (K961939). They have the same intended use, indications, sterilization method, packaging, materials, method of manufacture and design. DePuy believes that the subject DePuy S-ROM® Hip Prosthesis is substantially equivalent to the FDA-cleared DePuy S-ROM® Hip Stem (K961939).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2006

Ms. Anne Schuler
Senior Regulatory Affairs Specialist
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K061221
Trade/Device Name: S-ROM STD Hip Stem Prosthesis
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Codes: KWA, LZO, LPH
Dated: August 16, 2006
Received: August 17, 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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson

Mark N. Melkerson, M.S.
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): K061221
Device Name: DePuy S-ROM® Hip Stem Prosthesis

Indications for Use:

The DePuy S-ROM® Hip Stem Prosthesis is indicated for uncemented use as the femoral component in total hip arthroplasty (THA) for replacing the hip joints of patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicted for revision of previous hip arthroplasty and for patients with congenital hip dysplasia, *protrusion acetabuli*, slipped capital femoral epiphysis, and disability due to previous fusion.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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510(k) Number K061221