

K071059

510(k) SUMMARY

NAME OF FIRM: DePuy Orthopaedics Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Establishment Registration Number: 1818910

510(K) CONTACT: Kathy Harris
Director, Regulatory Affairs
Tel: (574) 372-7082
Fax: (574) 371-4987

NOV 09 2007

DATE PREPARED: October 20, 2007

TRADE NAME: DePuy SPA™ Porous Coated Proximal Sleeves

COMMON NAME: Femoral Proximal Sleeve

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

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

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

21 CFR 888.3310: Hip joint metal/polymer constrained cemented or uncemented prosthesis, Class II

DEVICE PRODUCT CODES: KWA, LZ0, MEH, LPH, KWZ

SUBSTANTIALLY

EQUIVALENT DEVICES: S-ROM™ 135 Porous Coated Femoral Stem Collar, K860207 cleared August 6, 1986

Coated ZT™ Proximal Sleeve, K934412 cleared June 3, 1994

DEVICE DESCRIPTION:

The SPA Porous Coated Proximal Sleeve is a component of the S-ROM Total Hip Replacement System. It is a porous coated Titanium femoral component with an elliptical shape that matches the contour of the bone and a stepped exterior to maximize compressive stresses. Fixation of the proximal sleeve to the femur is achieved by biologic fixation via tissue in-growth into the porous coating.

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INDICATIONS AND INTENDED USE:

The SPA Porous Coated Proximal Sleeve components of the S-ROM Total Hip System are indicated for use in total hip replacement procedures for 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 indicated for revision of previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis, and disability due to previous fusion.

The SPA Porous Coated Proximal Sleeves are intended for cementless use.

SUBSTANTIAL EQUIVALENCE:

The SPA Porous Coated Proximal Sleeve is identical in design, materials and manufacturing method to the S-ROM 135 Porous Coated Femoral Stem Collar, cleared in K860207 for cemented use only. The porous coating of the SPA Porous Coated Sleeve is identical to the porous coating used on the Coated ZT Proximal Sleeve, cleared in K934412 for cementless use. Based on these similarities, DePuy believes that the SPA Porous Coated Proximal Sleeve is substantially equivalent to the referenced predicate devices.

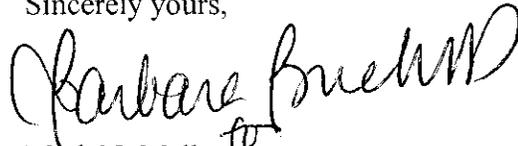
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Page 2 – Ms. Kathy Harris

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,

A handwritten signature in black ink, appearing to read "Barbara Buehler" with a small "to" written below it. The signature is written in a cursive style.

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): K071059

Device Name: DePuy SPA Porous Coated Proximal Sleeves

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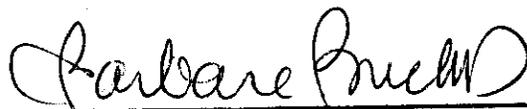
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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