K062654

SEP 29 2006

510(k) SUMMARY

NAME OF FIRM:	DePuy Orthopaedics Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration No.: 1818910
510(k) CONTACT:	Nancy Friddle Team Leader, Regulatory Affairs Tel: (574) 371-4923 Email: nfriddle@dpyus.jnj.com
TRADE NAME:	DePuy Sigma Cruciate Retaining (C/R) Porocoat® Femoral Components
COMMON NAME:	Total Knee Replacement Prosthesis
CLASSIFICATIONS:	888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis; Class II 888.3565 Knee joint patellofemorotibial polymer/metal porous coated uncemented prosthesis; Class II
DEVICE PRODUCT CODES:	JWH, MBH
SUBSTANTIALLY EQUIVALENT DEVICES:	PFC Sigma® Knee System (cleared as Darwin Knee System), K943462 PFC Cruciate Retaining Knee System, Size 1.5, K961685 AML® Proximally Coated Hip, K933787

DEVICE DESCRIPTION:
The Sigma C/R Porocoat Femoral Components are part of the Sigma Total Knee Replacement System. They are porous coated Co-Cr femoral components with an asymmetric trochlear groove, available in sizes 1.5- 6, in right and left versions. Fixation of the femoral component to the femur is achieved using either bone cement or by biologic fixation via tissue ingrowth into the porous coating.

INDICATIONS FOR USE:
The Sigma C/R Porocoat Femoral Components are intended for cemented or cementless use as the femoral components of a Total Knee Replacement system.

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Total Knee Replacement is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Candidates for total knee replacement include elderly patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant. Total knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to significant improvement in their quality of life.

SUBSTANTIAL EQUIVALENCE

The Sigma C/R Porocoat Femoral Components are identical in design to the Sigma Femoral Components cleared for cemented use only in K943462 and K961685. The Porocoat porous coating of the Sigma C/R Porocoat Femoral Components is identical to the Porocoat porous coating used on the LCS Knee Femoral Components, which were approved for cementless use in P830055 and on the AML Proximally Coated Hip cleared for cementless use in K933787.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 2006

DePuy Orthopaedics, Inc.
% Ms. Nancy Friddle
Team Leader, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K062654
Trade/Device Name: ~~DePuy Sigma Cruciate Retaining Porocoat~~® Femoral Components
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: September 6, 2006
Received: September 7, 2006

Dear Ms. Friddle:

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,

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): K062654

Device Name: DePuy Sigma Cruciate Retaining Porocoat® Femoral Components

Indications for Use:

The Sigma Cruciate Retaining Porocoat Femoral Components are intended for cemented or cementless use as the femoral components of a Total Knee Replacement system.

Total Knee Replacement is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Candidates for total knee replacement include elderly patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant. Total knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to significant improvement in their quality of life.

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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