K082500 #1/2

510(k) Summary

NOV 18 2008

Applicant / Sponsor:	DePuy Orthopaedics Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration No.: 1818910
Contact Person:	Nancy Friddle Project Leader, Regulatory Affairs Tel: (574) 371-4923 Fax: (574) 371-4987
Proprietary Name:	DePuy Sigma CR-F femoral component
Common Name:	Total Knee Replacement Prosthesis
Classification Name:	21 CFR 888.3560: Knee joint patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis, Class II
Product Code:	JWH
Substantially Equivalent Devices:	PFC Sigma® Knee System (cleared as Darwin Knee System), K943462 PFC Cruciate Retaining Knee System, Size 1.5, K961685

Device Description:

The Sigma CR-F femoral component is part of the PFC Sigma Total Knee Replacement System. It is a Co-Cr-Mo femoral component with an asymmetric trochlear groove, available in sizes 1.5 - 6, in right and left versions. The fixation surface is textured. It incorporates two pegs to provide additional stability and recessed cement pockets for enhanced cement fixation. These features have not changed from those on the predicate PFC Sigma CR femoral component.

Intended Use:

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.

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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.

The Sigma CR-F femoral component is intended to accommodate knee flexion to 150 degrees in those patients able to attain a high degree of knee flexion.

Indications:

The DePuy Sigma CR-F femoral component is intended for cemented use only.

Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant.

Summary of Technologies/Substantial Equivalence:

The Sigma CR-F femoral component has the same indications, materials, manufacturing process, sterilization and packaging as the previously cleared PFC Sigma CR femoral components. The design of the implant has been modified to provide more congruent articulation with the tibial insert during high flexion.

Non-Clinical Testing:

Comparisons of tibiofemoral contact area and pressure, range of motion analysis and constraint testing were performed to demonstrate the substantial equivalence of the Sigma CR-F femoral components to the predicate PFC Sigma CR femoral components.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the subject Sigma CR-F femoral components and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

NOV 18 2008

Re: K082500
Trade/Device Name: DePuy Sigma Cr-F Femoral Component
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: August 28, 2008
Received: August 29, 2008

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 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,

Mark N. Melkerson

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): K082500

Device Name: DePuy Sigma CR-F Femoral Component

Indications for Use:

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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

510(k) Number K082500