K073529

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:
DePuy Orthopaedics Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Establishment Registration No.: 1818910

510(K) CONTACT:
Nancy Friddle
Project Manager, Regulatory Affairs
Tel: (574) 371-4923
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JAN 24 2008

TRADE NAME:
DePuy Sigma PS Femoral Components

COMMON NAME:
Total Knee System, Femoral Components

CLASSIFICATION:
888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis; Class II

PRODUCT CODE:
JWH

SUBSTANTIALLY EQUIVALENT DEVICES:
Darwin Knee System, K950010
PFC Sigma Knee System (Size 1.5), K971189

DEVICE DESCRIPTION:
The Sigma PS Femoral Components are part of the Sigma Total Knee Replacement System. They are Co-Cr-Mo alloy cruciate substituting femoral components with an asymmetric trochlear groove, available in sizes 1.5 to 6, in right and left versions. The Sigma PS Femoral Components are available with or without lugs (pegs) on the fixation surface. The femoral components incorporate an intercondylar box and bolt hole, which allow the attachment of optional femoral stems for additional stability. The Sigma PS Femoral Components (without lugs) allow for the attachment of modular augments on the distal and posterior fixation surfaces. Fixation of the femoral component to the femur is achieved using bone cement.

INTENDED USE:
The Sigma PS Femoral Components are intended for cemented 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.

INDICATIONS FOR USE:

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.

BASIS FOR SUBSTANTIAL EQUIVALENCE:

The DePuy Sigma PS Femoral Components are a modification of the Sigma Femoral Components that were previously cleared as part of the Darwin Knee System (now called the Sigma Knee System) in K950010 and the PFC Sigma Knee System (now called the Sigma Knee System) in K971189. Based on similarities in indications, intended use, design, materials, method of manufacture and the results of dimensional comparisons, fatigue testing and patellofemoral contact area analysis, DePuy believes that the Sigma PS Femoral Components are substantially equivalent to the previously cleared femoral components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2008

DePuy Orthopaedics, Inc.
% Nancy S. Friddle
Project Manager, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, IN 46581-0988

Re: K073529
Trade/Device Name: DePuy Sigma PS Femoral Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: December 14, 2007
Received: December 17, 2007

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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K073529

Device Name: DePuy Sigma PS Femoral Components

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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)

Mark N Milhous

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

510(k) Number K073529