K070849

3. 510(K) SUMMARY

Applicant / Sponsor:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration No.: 1818910
Contact Person:	Nancy Friddle Team Leader, Regulatory Affairs Tel: (574) 371-4923 Fax: (574) 371-4987
Proprietary Name:	DePuy GCK Femoral and Tibial Components
Common Name:	Compartmental Knee Prosthesis System
Classification Name:	21 CFR 888.3560: Knee joint patellofemorotibial, polymer/ metal/polymer semi-constrained cement prosthesis, Class II
Product Codes:	NPJ, HRY
Substantially Equivalent Devices:	• DePuy GCK (K061648) • DePuy Sigma Unicompartmental Knee, submitted as the J&J PFC Unicondylar Knee System (K910968)

JUN 26 2007

Device Description:

The DePuy GCK is composed of unicompartmental femoral components, patellofemoral trochlear components, unicompartmental tibial components and patellar components. These components may be used in various combinations to create: a single unicompartmental femorotibial replacement for either the medial or lateral side of the knee; two unicompartmental femorotibial replacements for both the medial and lateral sides of the knee; a patellofemoral replacement; a bicompartmental patellofemorotibial replacement for the medial or lateral side of the knee; or a tricompartmental patellofemorotibial replacement for the medial and lateral sides of the knee.

The GCK unicompartmental femoral components are designed for individuals who require a higher than normal degree of flexion (up to 155°).

This submission describes design modifications to the previously cleared GCK unicompartmental femoral components and all polyethylene unicompartmental tibial components.

Intended Use / Indications:

The DePuy Graduated Compartmental Knee (GCK) 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.

The GCK is indicated for single or multi-compartmental knee replacement in skeletally mature individuals with osteoarthritis, posttraumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces or a history of gout or pseudogout. All GCK components are intended for CEMENTED USE ONLY.

Summary of Technologies/Substantial Equivalence:

The modified GCK unicompartmental femoral and all polyethylene unicompartmental tibial components have the same indications and intended use, the same articulating geometry, the same sizes and are manufactured from the same materials as the previously cleared GCK unicompartmental femoral and all polyethylene unicompartmental tibial components.

Non-Clinical Testing:

Finite Element Analysis was performed to demonstrate the substantial equivalence of the modified GCK unicompartmental femoral components to the predicate Sigma Unicompartmental femoral components and other clinically successful designs.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the subject modified GCK components and the predicate GCK components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2007

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

Re: K070849
Trade/Device Name: DePuy GCK Femoral and Tibial Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: NPJ, HRY
Dated: March 16, 2007
Received: March 28, 2007

Dear Ms. Friddle:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices 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 devices comply 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 devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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

2. INDICATIONS FOR USE

510(k) Number (if known): K070849

Device Name: DePuy GCK Femoral and Tibial Components

Indications for Use:

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The GCK is indicated for single or multi-compartmental knee replacement in skeletally mature individuals with osteoarthritis, posttraumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces or a history of gout or pseudogout. All GCK components are intended for CEMENTED USE ONLY.

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 K070849