AUG - 2 2007

510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Rhonda Myer Regulatory Affairs Telephone: (574) 371-4927 Facsimile: (574) 371-4987 Electronic Mail: Rmyer7@dpyus.jnj.com
DATE PREPARED:	May 16, 2007
PROPRIETARY NAME:	LPS Diaphyseal and Metaphyseal Sleeves
COMMON NAME:	Diaphyseal and Metaphyseal Sleeve Components
CLASSIFICATION:	888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
DEVICE PRODUCT CODE:	87 MBH, JWH
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Orthogenesis LPS System, K003182 DePuy LPS Metaphyseal Sleeve, K040281 DePuy Stability Hip Stem with Porocoat®, K934457

DEVICE DESCRIPTION:

The DePuy LPS Diaphyseal Sleeve is a modular, porous-coated, cone-shaped component designed to enhance the fit and fill of the diaphyseal femoral canal with distal femoral, proximal femoral and proximal tibial replacements. The existing LPS Metaphyseal Sleeve (K040281) is a modular, porous-coated, flared component designed for enhanced fit and fill of the metaphyseal region of the distal femur with femoral replacements. Both are manufactured from titanium alloy.

INTENDED USE AND INDICATIONS:

Intended Use:

The DePuy LPS Diaphyseal and Metaphyseal Sleeves are intended for use in primary and revision knee joint replacement in the treatment of patients presenting bone loss and deformity associated with bone tumors resection, trauma, infection, and difficult revision arthroplasty.

Indications for Use:
The diaphyseal sleeve is intended to enhance the fit and fill of the diaphyseal femoral canal with distal femoral, proximal femoral, and proximal tibial replacements. The metaphyseal sleeve is intended to enhance the fit and fill of the metaphyseal region of the distal femur with femoral replacements.

The DePuy LPS is intended for use in replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement. Specific diagnostic indications for use include:

- malignant tumors (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection and replacement;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement;
- revision cases for a failed previous prosthesis requiring extensive resection and replacement;
- severe trauma requiring extensive resection and replacement.

The LPS is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.

The S-ROM tibial tray and the non-porous coated straight and bowed stems are intended for cemented use only.

The diaphyseal and metaphyseal sleeves are intended for either **cemented** or **cementless** applications.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The substantial equivalence of the DePuy LPS Diaphyseal and Metaphyseal Sleeves is shown by the similarity in intended use, indications for use, materials and design to the existing DePuy Orthogenesis LPS, K003182 cleared on June 27, 2001, DePuy LPS Metaphyseal Sleeves, K040281 cleared on July 09, 2004, and DePuy Stability Hip Stem with Porocoat®, K934457.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Rhonda Myer
Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46582

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Re: K071417
Trade/Device Name: LPS Diaphyseal and Metaphyseal Sleeves
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: July 24, 2007
Received: July 25, 2007

Dear Ms. Myer:

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 Statement

510 (k) Number (if known): K071417

Device Name: LPS Diaphyseal and Metaphyseal Sleeves

Indications for Use:

The diaphyseal sleeve is intended to enhance the fit and fill of the diaphyseal femoral canal with distal femoral, proximal femoral, and proximal tibial replacements. The metaphyseal sleeve is intended to enhance the fit and fill of the metaphyseal region of the distal femur with femoral replacements.

The DePuy LPS is intended for use in replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement. Specific diagnostic indications for use include:

- malignant tumors (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection and replacement;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement;
- revision cases for a failed previous prosthesis requiring extensive resection and replacement;
- severe trauma requiring extensive resection and replacement.

The LPS is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.

The S-ROM tibial tray and the non-porous coated straight and bowed stems are intended for cemented use only.

The porous-coated diaphyseal and metaphyseal sleeves are intended for either **cemented** or **cementless** applications.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 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 K071417