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510(k) Summary
LPS

DePuy, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581

JUL 01 2004

A. Contact Person:

Dina L. Weissman, J.D.
Legal Consultant, Regulatory Affairs
TEL: (574) 371-4905, FAX (574) 371-4987, EMAIL dweissma@dpyus.jnj.com

B. Device Information:

Proprietary Name:	LPS
Common Name:	Total Knee Prosthesis Femoral Stem Prosthesis
Classification Name and Regulatory Class:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis: Class II per 21 CFR §888.3560 Hip joint metal/polymer semi-constrained cemented prosthesis: Class II per 21 CFR §888.3350
Product Code:	87 JWH, 87 JDI

C. Indications for Use (changes are in bold from those cleared in K003182):

The 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 distal femoral component, the tibial components, and the non-porous coated straight and bowed stems are intended for cemented use only.

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510(k) Summary (continued)
LPS

D. Device Description (unchanged from that cleared in K003182):

The LPS components are designed for the replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia. Unlike primary hip and knee systems, this system is used when the amount of resection and restoration is extreme (e.g. in oncology cases, endstage revision). A total femoral replacement is possible in those cases where no part of the femur can be salvaged.

E. Substantial Equivalence (same device as that cleared in K003182, only the material has changed to cobalt chrome):

The substantial equivalence of the LPS is substantiated by its similarity:

- in design, sterilization and packaging to the LPS (K003182 cleared on June 27, 2001).
- in materials to the S-ROM Noiles Rotating Hinge Knee (K870730 cleared on May 26, 1987),
- in indications for use to the Howmedica Global Modular Replacement System (GMRS) (K023087 cleared on December 16, 2002).

The determination of substantial equivalence for this device was based on a detailed device description and conformance with voluntary performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 01 2004

Ms. Dina L. Weissman, J.D.
Legal Consultant, Regulatory Affairs
DePuy, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581

Re: K033959
Trade/Device Name: LPS
Regulation Number: 21 CFR 888.3560, 21 CFR 888.3350
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis, Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH, JDI
Dated: April 20, 2004
Received: April 21, 2004

Dear Ms. Weissman:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
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): K033959
Device Name: LPS

Indications for Use: (changes from those cleared in K003182 are in bold)

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

(Posted November 13, 2003)

510(k) Number K033959