P1/2 K003182

JUN 2 7 2001

510(k) Summary
Orthogenesis LPS System

DePuy, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581

A. Contact Person:

Janet G. Johnson, RAC
Group Leader, Regulatory Submissions
(219) 371-4907

B. Device Information:

Proprietary Name:	Orthogenesis LPS System
Common Name:	Total Femur Replacement Prosthesis Proximal Tibial Replacement 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 Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis: Class II per 21 CFR §888.3358
Product Code:	87 JWH, 87 JDI, 87 LPH

C. Indications for Use:

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

- metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur;
- 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 of the proximal and/or distal femur;
- patients suffering from severe arthropathy of the hip and/or knee that does not respond to any conservative therapy or better alternative surgical treatment;
- revision cases requiring extensive resection(s) and replacements of the proximal, distal or total femur or proximal tibia.

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

D. Device Description:

The Orthogenesis LPS components are designed to be implanted for the replacement of the mid-shaft or intercalary 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:

The substantial equivalence of the Orthogenesis LPS System is substantiated by its similarity in indications for use, design, materials, sterilization and packaging to the S-ROM Noiles Rotating Hinge Knee (K870730, K896048, K905810 and K924940), the Sulzer Orthopedics MOST™ System (K973087), Wright Medical Segmented Orthopaedic System (SOS) (K933281) and the Howemedica MRS (K972401 and K965164).

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2001

Ms. Janet G. Johnson
Group Leader, Regulatory Submissions
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopedic Drive
Warsaw, Indiana 46581

Re: K003182
Trade Name: Orthogenesis LPS System
Regulatory Number: 888.3560 and 888.3350
Regulatory Class: II
Product Code: JWH and JDI
Dated: May 3, 2001
Received: May 4, 2001

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

510(k) Number (if known) K003182

Device Name **Orthogenesis LPS System**

Indications for Use

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- patients suffering from severe arthropathy of the hip and/or knee that does not respond to any conservative therapy or better alternative surgical treatment;
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The distal femoral and tibial components, tibial stems and non-porous coated femoral stems are intended for cemented use only.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

D Mitchell MD for CMW

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

510(k) Number K003182

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR §801.109)

(Optional Format 1-2-96)