NOV 25 1998

K983136

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR OF THIS 510(K):

DePuy, Inc.
P.O. Box 988
Warsaw, Indiana 46581-0988

510(K) CONTACT:

Sally Foust
DePuy Orthopaedics, Inc.
Sr. Regulatory Submissions Associate
(219) 372-7455; FAX (219) 267-7098
E-mail: Sally_Foust@ccgate.depuy.com

TRADE NAME: DePuy Luster Stem

COMMON NAME: Hip Prosthesis

CLASSIFICATION: Class II per 888.3350, Hip joint metal/polymer semi-constrained cemented prosthesis

DEVICE CODE: JDI

EQUIVALENT DEVICES: DePuy Cemented Hip Prosthesis (Endurance)(K942370)
CPT Hip Prosthesis (K960658)
Exeter Total Hip System (K974054, K980843)

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Luster Stem is a polished, distally tapered femoral stem with a proximal anterior/posterior flange, a medial 30° collar, and an oval driver hole in the lateral proximal shoulder. The DePuy Luster Stem is available in five sizes (1, 2, 3, 4, and 5) each with two offset options, standard and high, and is manufactured from forged cobalt chrome molybdenum alloy. The DePuy Luster Stem is indicated for cemented use as the femoral component in total hip arthroplasty for replacing the hip joint of a patient whose hip joint has been damaged by degenerative joint disease, fracture, or the failure of a previous arthroplasty.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Luster Stem is identical in design, material and intended use to the FDA cleared Endurance (K942370) femoral stem. Both stems are distally tapered femoral stems with a proximal anterior/posterior flange, a medial 30° collar, and an oval driver hole in the lateral proximal shoulder. Both stems have a 12/14mm self-locking male taper at the neck to allow for the use of interchangeable modular metal or ceramic femoral heads. Both stems are available in five sizes (1, 2, 3, 4, and 5) each with a standard and high offset option. Both stems accept a PMMA centralizer at the distal tip and may be used with a cement restrictor. Both stems are manufactured from forged cobalt chrome molybdenum alloy and are intended for cemented use as the femoral component in total hip arthroplasty for replacing the hip joint of patients whose hip joint has been damaged by degenerative joint disease, fracture, or the failure of a previous arthroplasty. The only difference

between the Luster stem and the FDA cleared Endurance stem is that the entire surface finish of the Luster stem is polished while the Endurance stem has a matte finish on the lateral and distal stem, and is grit blasted under the proximal flange.

The Luster stem is similar in material, design, and intended use to the FDA cleared CPT Hip Prosthesis in that the both stems are manufactured from cobalt chrome, are polished, and are intended for cemented use with the use of femoral canal centering devices (i.e., centralizers). The Luster stem is similar in design and intended use to the FDA cleared Exeter Total Hip System in that both stems are polished and are intended for cemented use with the use of femoral canal centering devices.

Based on similarities of design, materials and intended use, DePuy believes that the Luster Stem is substantially equivalent to the FDA cleared Endurance, CPT, and Exeter Hip Systems.

The following table summarizes the similarities:

	LUSTER	**ENURANCE (K942370)**	**CPT (K960658)**	**EXETER (K974054, K980843)**
Material	Cobalt-Chrome	Cobalt-Chrome	Cobalt-Chrome	316L Stainless Steel
Use	Cemented	Cemented	Cemented	Cemented
Design	Medial 30° Collar, Proximal Flange, Two Tapers, Polished Finish	Medial 30° Collar, Proximal Flange, Two Tapers, Matte Finish	Collarless, Slim Profile, Two Tapers, Polished Finish	Collarless, Slim Profile, Two Tapers, Polished Finish
Modular Heads	Yes	Yes	Yes	Yes
EndCaps/ Centralizers/ Cement Restrictors	Yes	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1998

Ms. Sally Foust
Senior Regulatory Submissions Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K983136
Trade Name: DePuy Luster Stem
Regulatory Class: II
Product Code: JDI
Dated: September 4, 1998
Received: September 8, 1998

Dear Ms. Foust:

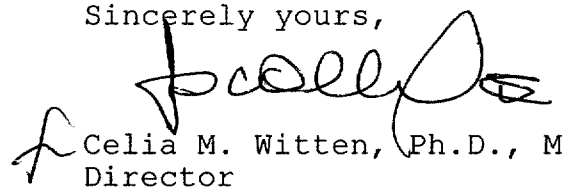
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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 and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K983136

Device Name: DePuy Luster Stem

Indications for Use:

The DePuy Luster Stem is indicated for cemented use as the femoral component in total hip arthroplasty for replacing the hip joint of a patient whose hip joint has been damaged by degenerative joint disease, fracture, or the failure of a previous arthroplasty.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983136