K980513

SUMMARY OF SAFETY AND EFFECTIVENESS

APR 14 1998

NAME OF FIRM: DePuy Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

510(k) CONTACT: Cheryl Hastings
Manager, Regulatory Submissions

TRADE NAME: Articul/eze Femoral Heads

COMMON NAME: Femoral Heads

CLASSIFICATIONS: 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis
888.3358: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

DEVICE PRODUCT CODES: 87 JDI and 87 LPH

SUBSTANTIALLY EQUIVALENT DEVICES: DePuy Focus Total Hip System (K883460)
DePuy Zirconia Articul/eze Femoral Balls (K952088)

DEVICE DESCRIPTION AND INTENDED USE:
The subject Articul/eze Femoral Heads are Co-Cr-Mo alloy femoral heads available in: a 22.225mm diameter with +4 and +7 neck lengths; a 26mm diameter with +4, +7 and +10mm neck lengths and a 36mm diameter with -2, +1.5, +5, +8.5 and +12mm neck lengths. All of the Articul/eze taper femoral heads have an internal 5°43' taper which mates with the 5°40' external taper on DePuy Articul/eze taper femoral stems.

The Articul/eze Femoral Heads are intended to be used with DePuy femoral hip stems with Articul/eze male tapers in cemented or cementless total hip arthroplasty for the indications of: a severely painful and/or severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis; avascular necrosis of the femoral head; acute traumatic fracture of the femoral head or neck; a failed previous surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement; and certain cases of ankylosis.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The listed substantially equivalent predicate device 510(k)s include Articul/eze taper cobalt-chrome alloy femoral heads in 28 and 32mm diameters and zirconia femoral heads in 26, 28 and 32mm diameters. The subject 22.225mm, 26mm and 36mm diameter Articul/eze taper cobalt-chrome femoral heads are being added to this line to give the surgeon a larger range of size and material options from which to select the best femoral head replacement for each patient. Based on similarities of design, material and intended use, DePuy believes that the subject Articul/eze Femoral Heads are substantially equivalent to the above listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 1998

Ms. Cheryl Hastings
Manager, Regulatory Submissions
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K980513
Trade Name: Articul/eze Femoral Heads
Regulatory Class: II
Product Code: JDI and LPH
Dated: February 6, 1998
Received: February 10, 1998

Dear Ms. Hastings:

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,

for 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) K980513

Device Name DePuy Orthopaedics Articul/eze Femoral Heads

Indications for Use:

The Articul/eze Femoral Heads are intended to be used with DePuy femoral hip stems with Articul/eze (12/14mm) male tapers in cemented or cementless total hip arthroplasty for the indications of: a severely painful and/or severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis; avascular necrosis of the femoral head; acute traumatic fracture of the femoral head or neck; a failed previous surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement; and certain cases of ankylosis.

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980513

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