K011367 JUN 15 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics, Inc. P.O. Box 988 700 Orthopaedic Drive Warsaw, Indiana 46581-0988
510(K) CONTACT:	Sally Foust Sr. Regulatory Associate (219) 371-4905 FAX (219) 371-4987
TRADE NAME:	Excel Fracture Cemented Hip Stem
COMMON NAME:	Hip Prosthesis
CLASSIFICATION:	Class II device per 21 CFR, 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis.
DEVICE PRODUCT CODE:	87 JDI
SUBSTANTIALLY EQUIVALENT DEVICE	Excel Fracture Cemented Hip Stem (cleared as Response 2000 Cemented Hip Stem) K00432

DEVICE DESCRIPTION AND INTENDED USE:
The subject device is a cobalt chromium molybdenum alloy modular and smooth stemmed prosthesis that is intended for cemented use to replace the femoral portion of the hip joint in total hip arthroplasty. Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions: 1) a severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia; 2) avascular necrosis of the femoral head; 3) acute traumatic fracture of the femoral head or neck; 4) failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement; and 5) certain cases of ankylosis.

BASIS OF SUBSTANTIAL EQUIVALENCE:
Except for being a smaller size, the size 1 Excel Fracture Cemented Hip Stem is identical in design, material, manufacturing process and intended use to the Excel Fracture Cemented Hip Stem cleared as Response 2000 Cemented Hip Stem.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2001

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

Re: K011367
Trade Name: Excel Fracture Cemented Hip Stem – Size 1
Regulation Number: 888.3350
Regulatory Class: II
Product Code: JDI
Dated: May 3, 2001
Received: May 4, 2001

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 at (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, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS

510(k) Number (if known) K011367

Device Name: Excel Fracture Cemented Hip Stem

INDICATIONS:
Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Cemented Components:
Femoral stem and acetabular cup total hip components labeled "For cemented use only" are indicated only for use with bone cement.

Concurrence of CDRH, Office of Device Evaluation

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

510(k) Number K011367

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