NOV 1 3 2002

K023453
page 1 of 1

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics, Inc. P.O. Box 988 700 Orthopaedic Drive Warsaw, IN 46581-0988
510(k) CONTACT:	Cheryl Hastings Director, Regulatory Affairs
TRADE NAME:	DePuy Summit FX Cemented Hip Prosthesis
COMMON NAME:	Total Hip Joint Replacement Prosthesis
CLASSIFICATION:	888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis; Class II
DEVICE PRODUCT CODE:	87 JDI
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy Summit Cemented Hip Prosthesis, K013352

DEVICE DESCRIPTION:
The Summit FX Cemented Hip Stem is a flanged, collared, tapered Cobalt-Chromium femoral stem with a smooth surface finish. The Summit FX Cemented Hip Stem is offered in 7 sizes with a constant offset. A distal PMMA centralizer helps assure that the stem is centered in the femoral canal. The stem is designed specifically to treat femoral head and neck fractures but can be used for any of the indications listed below.

INTENDED USE AND 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:

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

The Summit FX Cemented Hip Stem is intended for cemented use only.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The Summit FX Cemented Hip Stem is manufactured from the same material and has the same intended use as the Summit Cemented Hip Stem. The designs are similar, but the Summit FX Cemented Hip Stem is offered in only one offset and has no proximal centralizer beads. The Summit Cemented Hip Stem is offered in two offsets and includes proximal centralizer beads.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2002

Ms. Cheryl Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 4681-0988

Re: K023453
Trade Name: Summit FX Cemented Hip Stems
Regulation Number: 21 CRF 888.3350
Regulation Name: Hip Joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI
Dated: October 11, 2002
Received: October 15, 2002

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 Mark N Melkerson

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) K023453

page 1 of 1

Device Name DePuy Summit FX Cemented Hip Stem

Intended Use and 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:

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

The Summit FX Cemented Hip Stem is intended for cemented use only.

Concurrence of CDRH, Office of Device Evaluation

Mark N Milhous

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

510(k) Number K023453

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