K011489

JUL 3 1 2001

DePuy
a Johnson & Johnson company

510(k) Summary

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
PO Box 988
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USA
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Name of Sponsor:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

510(k) Contact:

Marcia J. Arentz
Senior Regulatory Associate
Phone: (219) 371-4944
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Trade Name:

Summit™ DuoFix™ Hip Prosthesis

Common Name:

Total Hip Joint Replacement Prosthesis with porous coating

Classification:

Class II Device per 21 CFR 888.3358:
Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis

Device Product Code:

Code: **87LPH** Prosthesis Hip Semi-constrained, Metal/Polymer, Porous Uncemented
No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for femoral hip stems.

Substantially Equivalent Device:

Hip Stem	
DePuy Titan Porocoat Hip Stem	K001991
Zimmer HGP Hip with HA/TCP coating	K980711
HA/Porous Coating	
DePuy TriFlange Acetabular Cup	K001277

Device Descriptions:

The Summit DuoFix™ Porous Hip prosthesis is a collarless, titanium, tapered femoral stem. The hip stem is manufactured from titanium (Ti-6Al-4V) and has a sintered commercially pure titanium bead porous coating (Porocoat®) applied to the stem with a thin layer of hydroxyapatite (HA) coating applied. The hip stem consists of 10 body sizes ranging in diameter from 7mm (Size 1) to 18mm (Size 10) with each body size having two offset options.

510(k) Summary (continued)

Intended use:

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.

Indications for use:

Total hip replacement is indicated in the following conditions:

1. 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 arthro-plasty, or total hip replacement.
5. Certain cases of ankylosis.

The Summit Duofix™ Hip Stem is indicated for cementless use and fixation by biological tissue ingrowth into the porous coating.

Substantial equivalence:

The Summit™ DuoFix™ Hip Prosthesis has the same intended use, is made from similar materials and has the same basic design as the predicate devices and is therefore substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 1 2001

Ms. Marcia J. Arentz
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K011489
Device Name: Summit DuoFix Hip Prosthesis
Regulation Number: 21 CFR 888.3358
Regulatory Class: II
Product Codes: LPH, MEH
Dated: May 14, 2001
Received: May 15, 2001

Dear Ms. Arentz:

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 legally marketed predicate 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 requirements, 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" (21CFR 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/dsma/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): K011489

Device Name: Summit™ DuoFix™ Hip Prosthesis

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Concurrence of CDRH, Office of Device Evaluation

[signature] for CDRH

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

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

510(k) Number K011489