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MAY - 5 2004

K040268/S1

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 EST REG No.: 1818910
510(K) CONTACT:	Abraham Wright Project Engineer Tel: (574) 372-7025 Fax: (574) 372-7101
TRADE NAME:	DePuy Preservation™ Unicondylar Tibia
COMMON NAME:	Unicompartmental Knee Prosthesis
CLASSIFICATION:	Knee joint femorotibial, metal/polymer semi-constrained cemented prosthesis (per 21 CFR 888.3530), Class II Device
DEVICE PRODUCT CODE:	87 HRY
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Preservation™ Unicondylar Knee System (K010810, cleared April 18, 2001) PFC® Sigma Uni-Compartmental Knee System (K954481, cleared October 10, 1996)

DEVICE DESCRIPTION:

The DePuy Preservation™ Unicondylar Tibia consists of a polyethylene insert that assembles to Co-Cr-Mo tibial tray. The insert has a posterior tab and anterior clips that connect to the peripheral rim of the tray. The undersurface of the tibia tray consists of a grooved single keel that runs anterior-posterior and is designed to provide fixation. It is available in five sizes, 1 through 5, and in three thicknesses, 9.5, 11.5, and 13.5 mm. All insert sizes are designed to articulate with all five sizes of the DePuy Preservation Unicondylar Knee femoral component.

INDICATIONS FOR USE:

The DePuy Preservation Unicondylar Knee is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Caution: This knee prosthesis component is intended for cemented use only. Candidates for unicondylar knee replacement include elderly patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant. In candidates for

unicondylar knee arthroplasty, only one side of the joint (the medial or lateral compartmental) is affected. Unicondylar knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total unicondylar knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom again in knee mobility may lead to an expectation of significant improvement in the quality of their lives.

SUBSTANTIAL EQUIVALENCE:

The fundamental scientific technologies of the DePuy Preservation Unicondylar Tibia Prosthesis have not changed from the FDA cleared DePuy Preservation Unicondylar Knee System (K010810) and PFC Sigma Uni-Compartmental Knee System (K954481). They have the same intended use, indications, sterilization method, packaging, method of manufacture, and similar materials and designs. DePuy believes that the DePuy Preservation Unicondylar Tibia is substantially equivalent to the FDA cleared DePuy Preservation Unicondylar Knee System (K010810) and the PFC Sigma Uni-Compartmental Knee System (K954481).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2004

Abraham Wright
Project Engineer
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K040268
Trade/Device Name: DePuy Preservation™ Unicondylar Tibia
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HRY
Dated: April 2, 2004
Received: April 5, 2004

Dear Mr. Wright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) 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.

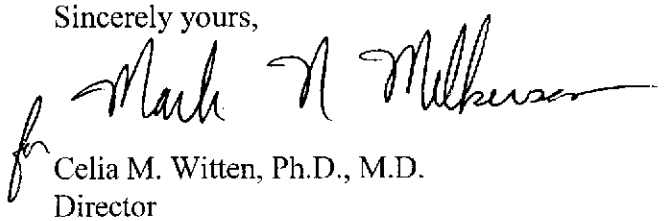
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



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

1.11

Indications for Use

510(k) Number (if known): K040268

Device Name: _____

Indications for Use:

The DePuy Preservation™ Unicondylar Knee is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Caution: This knee prosthesis component is intended for cemented use only. Candidates for unicondylar knee replacement include elderly patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant. In candidates for unicondylar knee arthroplasty, only one side of the joint (the medial or lateral compartmental) is affected. Unicondylar knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total unicondylar knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom again in knee mobility may lead to an expectation of significant improvement in the quality of their lives.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

for Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K040268