SEP 2 6 2003

K032151

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 Sigma Co-Cr Tibial Trays
COMMON NAME:	Total Knee Joint Replacement Prosthesis
CLASSIFICATION:	888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis; Class II
DEVICE PRODUCT CODE:	87 JWH
SUBSTANTIALLY EQUIVALENT DEVICE:	Johnson & Johnson Professional, Inc. (now DePuy) Darwin Knee System – K943462

DEVICE DESCRIPTION:
The DePuy Sigma Co-Cr Tibial Trays are Co-Cr-Mo alloy tibial trays similar in design to the Darwin tibial trays cleared in K943462. The Sigma Co-Cr Tibial Trays are intended for use with the Darwin (now PFC Sigma) femoral and patella components, previously cleared in K943462.

INTENDED USE AND INDICATIONS:
The Sigma Co-Cr Tibial Trays are intended for use in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention. The Sigma Co-Cr Tibial Trays are intended for cemented use only.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The Sigma Co-Cr Tibial Trays have the same basic design and the same intended use as the tibial trays of the Darwin Knee System. Like the Darwin trays, the Sigma Co-Cr trays can be used with the existing PFC Sigma femoral and patella components. The tibial tray material has been changed from forged Ti-6Al-4V alloy to forged Co-Cr-Mo alloy. Based on similarities in design, material, manufacturing method and intended use, DePuy believes that the Sigma Co-Cr Tibial Trays are substantially equivalent to the previously cleared trays of the Darwin Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2003

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

Re: K032151
Trade/Device Name: DePuy Sigma Co-Cr Tibial Trays
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: August 27, 2003
Received: August 28, 2003

Dear Ms. Hastings:

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,

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 Statement

510(k) Number (if known) K032151

Device Name DePuy Sigma Co-Cr Tibial Trays

Intended Use and Indications:

The Sigma Co-Cr Tibial Trays are intended for use in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention. The Sigma Co-Cr Tibial Trays are intended for cemented use only.

Concurrence of CDRH, Office of Device Evaluation

for Mark N Melkerson

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

510(k) Number K032151

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