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K033272

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 Tibial Inserts
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 DEVICES:	Johnson & Johnson Professional, Inc. (now DePuy) Darwin Knee System – K943462, K950010, K961685, K971189

DEVICE DESCRIPTION:
The DePuy Sigma Tibial Inserts are posterior lipped, cruciate retaining or stabilized UHMWPE tibial inserts with the same articular surface and basic geometry as the tibial inserts cleared in K943462, K950010, K961685 and K971189. Compared to the predicate inserts, the Sigma inserts have a larger distal mating surface to provide a tighter fit with the Sigma Tibial Trays. The locking mechanism has also been modified to reduce micromotion between the tibial insert and the tibial tray components. The Sigma Tibial Inserts are intended for use with the Sigma Co-Cr Tibial Trays previously cleared in K032151, and the Darwin femoral components, previously cleared in K943462.

INTENDED USE AND INDICATIONS:
The Sigma Tibial Inserts 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.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The Sigma Tibial Inserts have the same basic design and the same intended use as the tibial inserts of the Darwin Knee System. Minor design modifications have been made to the tibial inserts to provide a tighter fit with the Sigma Co-Cr Tibial Trays. Based on similarities in design, material, manufacturing method and intended use, DePuy believes that the Sigma Tibial Inserts are substantially equivalent to the previously cleared tibial inserts of the Darwin Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Cheryl Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, IN 45681-0988

Re: K033272
Trade/Device Name: DePuy Sigma Tibial Inserts
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: January 16, 2004
Received: January 20, 2004

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,

Celia M. Witten, Ph.D., M.D.
Division Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033272

Device Name: DePuy Sigma Tibial Inserts

Indications for Use:

The Sigma Tibial Inserts 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.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milleru

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

K033272

(Posted November 13, 2003)