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MAR 3 - 2005

SUMMARY OF SAFETY AND EFFECTIVENESS K043223

Name of Firm:	DePuy Orthopaedics, Inc. P.O. Box 988 700 Orthopaedic Drive Warsaw, IN 46581-0988
510(k) Contact:	Randa Franklin Sr. Regulatory Specialist
Trade Name:	DePuy CAS Knee Instrumentation
Common Name:	Computer Assisted Surgery (CAS) Knee Instrumentation
Regulatory Classification:	882.4560; Stereotaxic Instrument; Class II
Device Product Code:	HAW
Substantially Equivalent Device:	•~~K021306~~ K021306 VectorVision CT-Free Knee •K031337 Acumen Surgical Navigation System •K033011 Zimmer Ortho Guidance Systems-Knee Instruments

Device Description and Intended Use:
DePuy CAS Knee Instruments are computer recognized by application specific Ci TKR/UKR, VectorVision CT-Free Knee and VectorVision Knee hardware/software owned by BrainLAB. Together, instruments and hardware/software enable operational planning and navigation during minimally invasive orthopaedic knee replacement surgery. BrainLAB designed the Ci System exclusive to DePuy specific instrument/implant data tracked by flexible passive markers imposed on a virtual computer 3D image of the patient's bone. Landmarks on the bone surface are acquired to intraoperatively navigate the femoral and tibial cutting guides and implants for the most accurate position.

Basis of Substantial Equivalence:
Computer Assisted Surgical Knee Instruments are substantially equivalent to other legally marketed Class II stereotaxic instruments that are tracked through infrared tracking passive markers imposed onto computer images.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 - 2005

Ms. Randa Franklin
Senior Regulatory Specialist
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581

Re: K043223
Trade/Device Name: DePuy CAS Knee Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: February 4, 2005
Received: February 7, 2005

Dear Ms. Franklin:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

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

DePuy
A Johnson & Johnson company

Indications for Use

510(k) Number (if known): K043223

Device Name: DePuy CAS Knee Instruments

Indications for Use:

Instruments are tracked by a passive marker sensor system that acquires landmarks of the bone surface when interfaced with computer hardware and software. This enables a surgeon to accurately navigate the position of instrumentation by a virtual 3-D computer generated image for precise bone cuts during minimally invasive intraoperative knee reconstructive procedures. The system is indicated for any medical condition in which the use of stereotaxic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a long bone, can be identified relative to a CT or MR based model of the anatomy.

Example orthopaedic procedures for these instruments include, but are not limited to:

- Total Knee Replacement
- Unicondylar Knee Replacement
- Ligament Balancing
- Range of Motion Analysis
- Cruciate Ligament Surgery
- Patella Tracking

Prescription Use ✓ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

(Posted November 13, 2003)

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510(k) Number K043223