OCT 2 1 2005

K052178

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:	Randa Franklin Sr. Regulatory Specialist
Trade Name:	DePuy CAS Hip Instrumentation
Common Name:	Computer Assisted Surgery (CAS) Hip Instrumentation
Regulatory Classification:	882.4560; Stereotaxic Instrument; Class II
Device Product Code:	HAW
Substantially Equivalent Device:	•K040368 VectorVision Hip •K033223 Zimmer Ortho Guidance Systems – Hip Instruments •K033341 Smith & Nephew Image-Guided Surgical Instruments for Hip Applications •K021798 Image Guided Surgical Instruments for Hip Applications

Device Description and Intended Use:
DePuy CAS Hip Instruments are computer recognized by application specific VectorVision Hip software on Ci hardware platform, owned by BrainLAB. Together, instruments and hardware/software enable operational planning and navigation during orthopaedic hip surgery. The VectorVision Hip software is designed to read DePuy instrument and implant data and offers planning and navigating intra-operatively during surgery. BrainLAB designed the Ci hardware platform exclusively for DePuy. Instrument/implant data is 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 acetabular instrumentation and implants for the most accurate position.

Basis of Substantial Equivalence:
Computer Assisted Surgical Hip Instruments are substantially equivalent to other legally marketed Class II stereotaxic instruments by means of tracking patient anatomy through infrared passive markers imposed onto computer images.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1 2005

Randa Franklin
Sr. Regulatory Specialist
DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K052178
Trade/Device Name: DePuy CAS Hip Instrumentation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: October 4, 2005
Received: October 5, 2005

Dear Mr. 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,

for

Mark N. Melkerson
Acting 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): K052178

Device Name: DePuy CAS Hip Instrumentation

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 preparation during intraoperative hip 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 Joint Replacement (TJR)
- Revision Surgery of TJR
- Tumor resection and Bone/Joint Reconstruction

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

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

510(k) Number K052178