K071135

MAY 23 2007

# 510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

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|---|---|
| **NAME OF SPONSOR:** | DePuy Orthopaedics, Inc.<br>700 Orthopaedic Drive<br>Warsaw, Indiana 46582<br>Establishment Registration Number: 1818910 |
| **510(K) CONTACT:** | Natalie S. Heck<br>Manager, Regulatory Affairs<br>Telephone: (574) 372-7469<br>Facsimile: (574) 371-4987<br>Electronic Mail: Nheck@dpyus.jnj.com |
| **DATE PREPARED:** | April 20, 2007 |
| **PROPRIETARY NAME:** | DePuy Ci™ Hip Instrumentation |
| **COMMON NAME:** | Computer Assisted Surgery Instruments |
| **CLASSIFICATION:** | Class II per 21 CFR 882.4560, Stereotaxic Instrument |
| **DEVICE PRODUCT CODE:** | 84 HAW |
| **SUBSTANTIALLY EQUIVALENT DEVICE:** | DePuy CAS Hip Instrumentation, K052178<br>BrainLAB VectorVision Hip Software, K05221 |

## DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Ci™ Hip Instruments are reusable manual orthopaedic surgical instruments modified with a navigation adapter for use with BrainLAB's VectorVision Hip version software on the DePuy Ci hardware platform.

These instruments are designed for either manual or computer navigation use. The BrainLAB Starlock arrays and marble-sized optical spheres enable the instruments to interface with computer assisted imaging hardware and software. The VectorVision Hip software is designed to read DePuy instrument and implant data and offers planning and navigating intra-operatively during surgery.

Instruments are tracked by marble sized marker spheres attached to a reference array creating a passive marker sensor system that acquires landmarks of the bone surface when interfaced with computer hardware and software. A virtual 3-D computer image is

generated enabling a surgeon to accurately navigate the position of instrumentation for precise bone preparation during intraoperative hip surgery.

**INDICATIONS FOR USE:**

The DePuy Ci Hip 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 total hip replacement (THR) procedures. The system is indicated for total hip replacement procedures 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

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The subject DePuy Ci Hip Instrumentation is substantially equivalent to the existing DePuy CAS Hip Instrumentation (K052178), based on the similarities in design, intended use, materials, sterility, and use of computer navigation, and does not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Natalie S. Heck
Manager, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

MAY 23 2007

Re: K071135
Trade/Device Name: DePuy Ci™ Hip Instrumentation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: April 20, 2007
Received: April 23, 2007

Dear Ms. Heck:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

510 (k) Number (if known): K071135

Device Name: DePuy Ci™ 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 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 if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

**510(k) Number** k071135