MAR 2 1 2006

K060121

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Lester F. Padilla

Proprietary Name: Biomet Pre-Calibrated Computer Aided Surgery (CAS) Navigation Instruments for Hip Applications

Common Name: Stereotaxic Instrument

Classification Name: Instrument, Stereotaxic (21 CFR 888.4560)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
1. Smith & Nephew Image-Guided Instruments for Hip Applications (K033341)
2. BrainLAB VectorVision® Hip 3.0 Image Guided Surgery System (K040368)
3. DePuy CAS Hip Instrumentation (K052178)
4. BrainLAB VectorVision® Hip Software on the Ci platform (K052213)

Device Description: The Biomet Pre-Calibrated Computer Aided Surgery (CAS) Navigation Instruments for Hip Applications are reusable conventional manual orthopedic surgical instruments modified with a navigation adapter for use with the BrainLAB VectorVision® Hip Image Guided Surgery System.

Intended Use: The Biomet Pre-Calibrated Computer Aided Surgery (CAS) Navigation Instruments for Hip Applications are intended to assist the surgeon in precisely locating anatomical structures in either open or percutaneous procedures. The Biomet Pre-Calibrated Surgical Navigation Instruments for Hip Applications are indicated for use in surgical hip procedures, in which the use of stereotactic surgery may be appropriate, and where a reference to a rigid anatomical structure such as long bone can be identified relative to a CT based model or by an individual 3D model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. These procedures include but are not limited to acetabular cup replacement as part of a partial or total hip arthroplasty (primary or revision).

Summary of Technologies: The Pre-Calibrated Surgical Navigation Instruments for Hip Applications and the predicate devices all have similar technological characteristics.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

Prepared: January 4, 2006

All trademarks are property of Biomet, Inc. except for VectorVision, which is a trademark of BrainLAB AG, Germany

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 1 2006

Biomet Manufacturing Corporation
c/o Mr. Lester F. Padilla
Regulatory Affairs Associate
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K060121
Trade/Device Name: Biomet Pre-Calibrated Computer Aided Surgery (CAS) Navigation Instruments for Hip Applications
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: January 13, 2006
Received: January 17, 2006

Dear Mr. Padilla:

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.

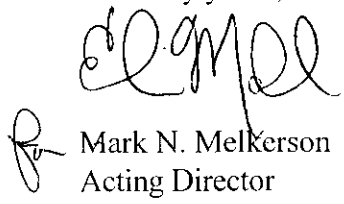
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Acting 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): K060121

Device Name: Biomet Pre-Calibrated Computer Aided Surgery (CAS) Navigation Instruments for Hip Applications

Indications For Use:

The Biomet Pre-Calibrated Computer Aided Surgery (CAS) Navigation Instruments for Hip Applications are intended to assist the surgeon in precisely locating anatomical structures in either open or percutaneous procedures. The Biomet Pre-Calibrated Computer Aided Surgery (CAS) Navigation Instruments for Hip Applications are indicated for use in surgical hip procedures, in which the use of stereotactic surgery may be appropriate, and where a reference to a rigid anatomical structure such as long bone can be identified relative to a CT based model or by an individual 3D model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. These procedures include but are not limited to acetabular cup replacement as part of a partial or total hip arthroplasty (primary or revision).

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO___
(Part 21 CFR 801 Subpart D) (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 K060121