

K060727

510 (k) Summary of Safety and Effectiveness for VectorVision® hip Software

Manufacturer:

Address: BrainLAB AG
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85622 Feldkirchen
Germany
Phone: +49 89 99 15 68 0
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AUG 21 2006

Contact Person: Mr. Per Persson

Summary Date: July 7th, 2006

Device Name:

Trade name: VectorVision® hip Software
Common/Classification Name: VectorVision, BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device:

Vector Vision® HIP 3.0 (K040368)

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II

Intended Use:

BrainLAB VectorVision is intended to be an intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. The system is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-ray, MR based model of the anatomy. The system aids the surgeon to accurately navigate a hip endoprosthesis to the preoperatively or intraoperatively planned position.

Example orthopedic surgical procedures include but are not limited to:

Total Joint Replacement (TJR)
Revision surgery of TJR
Minimal Invasive Orthopedic Surgery
Tumor resection and bone/joint reconstruction

Device Description:

BrainLAB VectorVision® hip Software is intended to enable operational planning and navigation in orthopedic surgery. It links a surgical instrument, tracked by flexible passive markers to virtual computer image space on an individual 3D-model of the patient's bone, generated through acquiring multiple landmarks on the bone surface either by a pointer probe or by acquiring pairs of registered fluoroscopic images. VectorVision® hip Software uses the registered landmarks to navigate the needed surgical tools like cup reamer, cup inserter, stem rasp, bone saw and the implant to the planned position. If no implant data is available it is possible to provide information in order to achieve a generally targeted alignment relative to the bone orientation as defined by the operating surgeon.

VectorVision® hip Software allows 3-dimensional reconstruction of the relevant mechanical axes and planes of femur and pelvis and alignment of the implants. The VectorVision® hip Software has been designed to read in data of implants and tools if provided by the implant manufacturer and offers to individually choose the prosthesis during each surgery. The VectorVision® hip Software registers the patient data needed for planning and navigating the surgery intra-operatively within the CT free module. The System can be used to generally align tool orientations according to the anatomy described and defined by the landmarks acquired by the surgeon.

Substantial equivalence:

VectorVision® hip Software has been verified and validated according to BrainLABs procedures for product design and development. The validation proves the safety and effectiveness of the system.

The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with predicate devices such as the 510(k)-clearance of:

- VectorVision® Hip 3.0 (K040368)
- VectorVision® Trauma (K012448)
- Hip Module for the StealthStation System (K021980)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2006

BrainLAB AG
% Mr. Peter Drumm
Project Manager
Ammerthalstrasse 8
85551 Heimstetten
Germany

Re: K060727
Trade/Device Name: VectorVision[®] hip
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW
Dated: July 28, 2006
Received: August 3, 2006

Dear Mr. Drumm:

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.

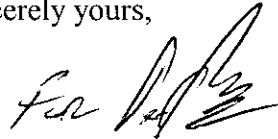
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

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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

510(k) Number (if known): K 060727

Device Name: VectorVision® hip

Indications For Use:

BrainLAB VectorVision is intended to be an intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. The system is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-ray, MR based model of the anatomy. The system aids the surgeon to accurately navigate a hip endoprosthesis to the preoperatively or intraoperatively planned position.

Example orthopedic surgical procedures include but are not limited to:

- Total Joint Replacement (TJR)
- Revision surgery of TJR
- Minimal Invasive Orthopedic Surgery
- Tumor resection and bone/joint reconstruction

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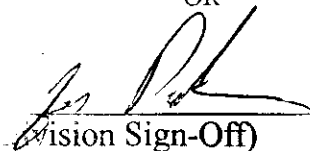
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format I-2-96)



(Signature Sign-Off)

Division of General, Restorative
and Prosthetic Devices

510(k) Number K 060727