

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

K063028

Manufacturer:

Address: BrainLAB AG
Kapellenstrasse 12
85622 Feidkirchen
Germany
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Contact Person: Mr. Per Persson

Summary Date: September 26th, 2006

Device Name:

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

Predicate Device:

VectorVision® hip (K 040368)
VectorVision® osteotomy (K042513)

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

Intended Use:

BrainLAB's VectorVision® hip SR is intended as an intraoperative image-guided localization system. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a VectorVision® navigation station. The image data is provided either in the form of preoperatively-acquired patient images or in the form of an individual 3D model of the patient's bone, which is generated by 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 appropriate 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, or MR-based model of the anatomy. The system aids the surgeon in accurately navigating a hip endoprosthesis to the preoperatively or intraoperatively planned position.

Example orthopedic surgical procedures include but are not limited to:

- Partial/hemi-hip resurfacing

Device Description:

BrainLAB's VectorVision® hip SR is intended to enable operational planning and navigation in orthopedic hemi resurfacing 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, which is generated through acquiring multiple landmarks on the bone surface. VectorVision® hip SR uses the registered landmarks to navigate the initial pin insertion into the femur with a pre-calibrated drillguide to the planned position.

VectorVision® hip SR allows 3-dimensional reconstruction of the relevant anatomical axes and planes of the femur and alignment of the implants. The VectorVision® hip SR 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. 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. The VectorVision® hip SR software registers the patient data needed for planning and navigating the surgery intra-operatively without CT-based imaging. 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 SR has been verified and validated according to BrainLAB's 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 the predicate device **Vector Vision® hip** (K 040368) and **Vector Vision® osteotomy** (K042513).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BrainLAB AG
% Rainer Birkenbach
Executive Vice President
Kapellenstrasse 12
85622 Feldkirchen
Germany

DEC 12 2006

Re: K063028
Trade/Device Name: VectorVision[®] hip SR
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: September 28, 2006
Received: October 2, 2006

Dear Rainer Birkenbach:

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.

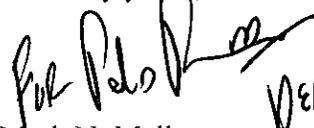
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



DEPUTY
DIRECTOR

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

510(k) Number (if known): K063028

Device Name: VectorVision® hip SR

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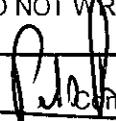
- Partial/hemi-hip resurfacing

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 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**

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