

K041899

OCT 6 - 2004

510 (k) Summary of Safety and Effectiveness for VectorVision® uni-knee

Manufacturer:

Address: BrainLAB AG
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85551 Heimstetten
Germany
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Contact Person: Mr. Rainer Birkenbach

Summary Date: October 5, 2004

Device Name:

Trade name: VectorVision® uni-knee
Common/Classification Name: VV uni-knee; BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device:

Vector Vision® CT-free Knee (K021306)
Ci TKR/UKR (K031770)

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 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, MR based model of the anatomy. The system aids the surgeon to accurately navigate a knee endoprosthesis to the intraoperatively planned position. Ligament balancing and measurements of bone alignment are provided by VectorVision® uni-knee.

Example orthopedic surgical procedures include but are not limited to:

Knee Procedures:
Unicondylar Knee Replacement
Ligament Balancing
Range of Motion Analysis
Patella Tracking

Device Description:

BrainLAB VectorVision® uni-knee is intended to enable 3 dimensional implant planning and navigation for unicompartmental orthopedic knee surgery. The SW links a surgical instrument tracked by passive markers to a 3D-model of the patient's bone, which is generated by acquiring multiple landmarks on the bone surface. VectorVision® uni-knee uses the registered landmarks to navigate the femoral and tibial cutting guides to the pre-planned position.

VectorVision® uni-knee allows 3-dimensional reconstruction of the mechanical axes and alignment of the implants. The VectorVision® uni-knee software has been designed to read in implant data and tool data from different manufacturers and offers to individually choose the prosthesis during each surgery. The VectorVision® uni-knee software registers the patient data needed for planning and navigating intra-operatively. No preoperative CT-scanning is necessary.

Substantial equivalence:

VectorVision® uni-knee 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 includes the Accuris Tibiofemoral Cutting Block Adapter and was found to be substantially equivalent with predicate devices such as the 510(k)-clearance of VectorVision® CT-free knee (K 021306) and Ci TKR/UKR (K031770).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2004

Mr. Rainer Birkenbach
BrainLab AG
Ammerthalstrasse 8
85551 Heimstetten
Germany

Re: K041899
Trade/Device Name: VectorVision Uni-Knee
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: September 3, 2004
Received: September 8, 2004

Dear Mr. 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.

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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,

for *Miriam C. Provost*
Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K041899Device Name: VectorVision uni-knee**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 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, MR based model of the anatomy. The system aids the surgeon to accurately navigate a knee endoprosthesis to the intraoperatively planned position. Ligament balancing and measurements of bone alignment are provided by VectorVision® uni-knee.

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Knee Procedures:

Unicondylar Knee Replacement
Ligament Balancing
Range of Motion Analysis
Patella Tracking

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)

(Optional Format I-2-96)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K041899