JAN 13 2005

K042512 1/2

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

Manufacturer:

Address: BrainLAB AG
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85551 Heimstetten
Germany
Phone: +49 89 99 15 68 0
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Contact Person: Mr. Rainer Birkenbach

Summary Date: September 09, 2004

Device Name:

Trade name: VectorVision® ACL

Common/Classification Name: VectorVision, BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device:
Vector Vision® Trauma (K012448)
Vector Vision® CT free knee (K021306)

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

Indications For Use:

BrainLAB VectorVision ACL is intended to be an intra-operative image-guided localization system to enable minimally-invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtua computer image space on a patient's intra-operative image data which is processed by a VectorVision workstation. A virtual individual 3D-surface model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface, supplements the 2D information of the intra-operative image data.

The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a bone structure, such as tibia and femur, can be identified relative to a CT fluoroscopic, x-ray or MR-based model of the anatomy.

An example procedure includes but is not limited to:
Planning and drill-tunnel guidance of interosseous canals for ligament repair on the knee.

Device Description:

BrainLAB VectorVision® ACL is a touchscreen-based-intra-operative planning and navigation software, designed for use in anterior cruciate ligament surgery. It is intended to support the surgeon in the planning and drilling of ideal graft canals for the replacement of a torn Anterior Cruciate Ligament (ACL). VVACL uses registered fluoroscopic images and their defined exact spatial position in relation to the patient. These images are acquired intra-operatively using a C-arm. A virtual individual 3D-surface model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface, supplements the 2D information of the intra-operative image data.

Substantial equivalence:

VectorVision® ACL 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 510(k)-clearance of VectorVision® CT-free knee (K 021306) and VectorVision® Trauma (K012448).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2005

Mr. Per Persson
Quality Manager
BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany

Re: K042512
Trade/Device Name: VectorVision ACL
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: December 23, 2004
Received: December 30, 2004

Dear Mr. Persson:

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,

Miriam C. Provost

for 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): **K042512**

Device Name: VectorVision ACL

Indications For Use:

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The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a bone structure, such as tibia and femur, can be identified relative to a CT, fluoroscopic, x-ray or MR-based model of the anatomy.

An example procedure includes but is not limited to:

Planning and drill-tunnel guidance of interosseous canals for ligament repair on the knee.

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)

Miriam C Provost

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

510(k) Number K042512