K021306

OCT 2 5 2002

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

Manufacturer:

Address: BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany
Phone: +49 89 99 15 68 0
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Contact Person: Mr. Rainer Birkenbach

Summary Date: October 22, 2002

Device Name:

Trade name: VectorVision® CT-free knee

Common/Classification Name: VectorVision® CT-free knee, BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device:
Vector Vision® Knee (K 010612)

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 endoprothesis to the intraoperatively planned position. Ligament balancing and measurements of bone alignment are provided by VectorVision® CT-free knee.

K021306

Example orthopedic surgical procedures include but are not limited to:

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

Device Description:
BrainLAB VectorVision® CT-free knee 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, which is generated through acquiring multiple landmarks on the bone surface. VectorVision® CT-free knee uses the registered landmarks to navigate the femoral and tibial cutting guides and the implant to the planned optimally position.

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

Substantial equivalence:
VectorVision® CT-free 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 was found to be substantially equivalent with predicate devices such as the 510(k)-clearance of VectorVision® knee (K 010612).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2002

BrainLAB AG
Rainer Birkenbach
Executive Vice President
Ammerthalstrasse 8
85551 Heimstetten
Germany

Re: K021306
Trade/Device Name: VectorVision CT-Free Knee
Regulation Number: 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW
Dated: July 25, 2002
Received: August 1, 2002

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.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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): K021306

Device Name: VectorVision® CT-free 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 endoprothesis to the intraoperatively planned position. Ligament balancing and measurements of bone alignment are provided by VectorVision® CT-free Knee.

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Patella Tracking

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K021306