K012448

MAR 1 4 2002

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

Manufacturer:
BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany
Phone: +49 89 99 15 68 0
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Device Name:

Trade Name:	Vector Vision® Trauma
Common/Classification Name:	VectorVision, BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device:
VectorVision^{2}® (K983831)
VectorVision cranial, ENT, spine (K003589)

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

Indications for use:
BrainLAB VectorVision Trauma is intended to be a pre- and 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 a patient's pre- or intraoperative image data being processed by a VectorVision workstation. 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 bone structure like tubular bones, pelvic, calcaneus and talus, or vertebra, can be identified relative to a CT, fluoroscopic, X-ray or MR based model of the anatomy.

Example procedures include but are not limited to:

Spinal Procedures and spinal implant procedures such as pedicle screw placement.
Pelvis and acetabular fracture treatment such as screw placement or ilio-sacral screw fixation.
Fracture treatment procedures, such as intramedullary nailing or plating or screwing or external fixation procedures in the tubular bones.

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Device Description:

BrainLAB VectorVision® Trauma is intended to enable operational navigation in spinal, orthopedic and traumatologic surgery. It links a surgical instrument, tracked by flexible passive markers to virtual computer image space on a patients intraoperative image data being processed by a VectorVision workstation.

VectorVision® Trauma allows navigation of intraopative acquired images considering patients movement in correlation to calibrated surgical instruments. This allows implant positioning, screw placement and bone reduction in different views and reduces the need for treatments under permanent fluoroscopic radiation.

Substantial equivalence:

VectorVision® Trauma 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 VectorVision² (K983831).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2002

Mr. Rainer Birkenbach
BrainLab AG
Ammerthalstrasse 8
85551 Heimstetten
Germany

Re: K012448
Trade/Device Name: VectorVision Trauma
Regulation Number: 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: II
Product Code: HAW
Dated: December 20, 2001
Received: December 26, 2001

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" (21CFR 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): K012448

Device Name: VectorVision Trauma

Indications For Use:

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(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 K012448