K023651

FEB 17 2004

510 (k) Summary of Safety and Effectiveness for VectorVision Cranial/ENT

Manufacturer:

Address:	BrainLAB AG Ammerthalstrasse 8 85551 Heimstetten Germany Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 33
Contact Person:	Mr. Rainer Birkenbach
Summary Date:	Nov 17, 2003

Device Name:

Trade name:	VectorVision Cranial / ENT
Common/Classification Name:	Image Guided Surgery System, CAS / Stereotaxy Instrument

Predicate Device:
Vector Vision® ² (K 983831)
VectorVision Cranial / ENT / Spine (K003589)

Device Classification Name: Stereotaxy Instrument
Regulatory Class: Class II

Indications For Use:
VectorVision Cranial/ENT 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 patient image data being processed by the 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 long bone, or vertebra, can be identified relative to a CT, CTA, X-ray, MR, MRA and ultrasound based model of the anatomy.

Example procedures include but are not limited to:

Cranial Procedures:
Cranial biopsies
Tumor resections
Craniotomies/ Craniectomies
Skull base procedures
Thalamotomies/Pallidotomies

ENT Procedures:
Transphenoidal procedures
Intranasal procedures
Sinus procedures, such as Maximillary antrostomies, Ethmoidectomies, Spheno-idotomies / Sphenoid explorations, Turbinate resections and Frontal sinusotomies

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Device Description

The tracking system consists of two infrared light sources and infrared cameras. Around each camera lens is an array of infrared LED's, which flood the field of view with infrared light. The infrared light is reflected by retro-reflective material (reflects light back to the light source) to the two cameras. This tracking principle does not require electrical cords on the reflecting targets and is therefore called passive tracking system.

Software

The tracking system sends the targets 2D and 3D position to the navigation workstation. The navigation software uses this information considering known geometric information for tracking the 3D position of probes and other surgical tools with attached retro-reflective marker arrays.
To link the virtual diagnostic image space within the navigation system to the surgical environment, the surgeon selects points on the patient using a tracked pointer probe. The selected points are stored and interpreted by the computer and related to corresponding points extracted from the diagnostic image data sets.
A different option to register the patient anatomy to the virtual image space is provided by means of a laser scanning device. With this laser device the surface of the patients head is scanned meanwhile the IR camera system picks up the laser reflections on the patients skin. By creating a virtual surface model out of the 3D coordinates of these laser points the software matches patient data set and the patient position inside the operating room.

Another contactless registration method for MR image data is provided by a localizer geometry of MR markers, which is - by fixed relation to the patient and the reference array and by automatic registration of the markers - a direct link to the virtual image space. In combination with the integration of data transfer functionalities this registration method is preferred for intra-operative MR data use.

The device visualizes patient data including the option to overlay multiple data sets, outlined structures and trajectories. The area of interest is displayed in the virtual computer image space in 2D- and 3D-representations.

For the localization of any area or structure in the patient's body a pointer tool is used or any other surgical instrument with attached retro-reflective marker arrays. A special device is available to precisely register any surgical instrument for navigation.

Surgical microscopes are integrated similarly as a virtual pointer tool by a mounted marker array and a software interface. With image injection modules and video display a close co-operation of navigation system and microscope is achieved. Other intraoperative image sources like ultrasound transducers and endoscopes are tracked and integrated similarly and can be controlled within the software to be displayed on an external display device for the purpose of non-diagnostic image information overview.

For sending requests and commands to external software and computers via network, e.g. for controlling the content of the external display device, a general communication interface is integrated into the navigation software.

Hardware

The VectorVision hardware platforms consist of electronic hardware combined in different housings which allow to adapt to the respective needs in certain OR settings. There are infrared cameras and a touch-screen, signal transmission cables, the navigation workstation itself and cable interfaces to external devices (e.g. microscopes). Currently there are 3 platforms available: VectorVision^2, VectorVision Compact and VectorVision Sky. With the VectorVision Sky ceiling mounted articulated arms carry camera and touch-screen. The VectorVision Sky can be prepared for use in magnet-resonance environments with shielded RF cage e.g. by providing optical signal transmission. Interfacing external devices such as a microscope and/or a surgical endoscope is realized by interface elements in a wall panel box.

VectorVision does not contain implants but provides a system for accurate implant placement.

Substantial equivalence

VectorVision Cranial / ENT 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 VectorVision^2 (K983831) and VectorVision Cranial / ENT / Spine (K003589).

Part 3 Combination Product Algorithm
(Revised March 12, 2003)

Quick Reference Table[1] -- Part 3 Combination Product Categories

Category Number	Type of Part 3 Combination Product
N	Not a Part 3 Combination Product
1	Convenience Kit or Co-Package
2	Prefilled Drug Delivery Device/System (syringe, patch, etc.)
3	Prefilled Biologic Delivery Device/System (syringe, patch, etc.)
4	Device Coated/Impregnated/Otherwise Combined with Drug
5	Device Coated or Otherwise Combined with Biologic
6	Drug/Biologic Combination
7	Separate Products Requiring Cross Labeling
8	Possible Combination Based on Cross Labeling of Separate Products (Temporary Code)
9	Other Type of Part 3 Combination Product (e.g., Drug/Device/Biologic Product)

Note: The above categories are intended to be mutually exclusive. If a product meets the definition of more than one category, select the category that you believe best describes the regulatory issues associated with the combination product.

Overview: A 21 CFR Part 3 combination product is a product comprised of components usually regulated under different authorities. It may be a drug combined with a device, a biologic combined with a device, or a drug combined with a biologic. Cells or tissues that are not eligible for regulation solely as cells or tissues because they are combined with a drug or a device (except for a sterilizing, preserving, or storage agent) may also be combination products. Discuss with your Center's product jurisdiction officer.

Combination products include those where the components are[2]:

- Physically or chemically combined OR
- Separate but provided/packaged as a unit OR

[1] Category descriptions and examples follow.
[2] See 21 CFR § 3.2(e) for complete definition. [will link to definition on OCP website]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2004

Mr. Ranier Birkenbach
BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany

Re: K023651
Trade/Device Name: VectorVision Cranial/ENT
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: November 17, 2004
Received: November 19, 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.

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 (301) 594-4659. 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 Mark N. Melkerson

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

Indications for Use

510(k) Number (if known): **K023651**

Device Name: **VectorVision Cranial/ENT**

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Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

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

510(k) Number K023651