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510 (k) Summary of Safety and Effectiveness for the Cranial Image Guided Surgery System

Manufacturer:

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Germany
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Contact Person: Mr. Alexander Schwiersch

Summary Date: May 04, 2010

Device Name:

Trade name:
VectorVision cranial
VectorVision ENT
Kolibri cranial
Kolibri ENT
Cranial Essential
Cranial Unlimited
ENT Essential
ENT Unlimited

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

Predicate Device:
Cranial Image Guided Surgery System K082060

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

This submission does not change the indications for use for the predicate devices.

1. **Intended Use:**

The BrainLAB Cranial IGS System is intended to be an intra-operative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a magnetic sensor system or a passive marker sensor system to a virtual computer image space on patient image data being processed by the IGS 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.

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Example procedures include but are not limited to:

Cranial Procedures:
Tumor resections
Skull base surgery
Cranial biopsies
Craniotomies/ Craniectomies
Pediatric Catheter Shunt Placement
General Catheter Shunt Placement
Thalamotomies/ Palliodotomies

ENT Procedures:
Transphenoidal procedures
Maximillary antrostomies
Ethmoidectomies
Spheno-idotomies/ sphenoid explorations
Turbinate resections
Frontal sinusotomies
Intranasal procedures

Modification:
The added accessory "Disposable Stylet" is a pre-calibrated guiding stylet for free handed and navigated placement of catheters/ shunts or similar products.

2. **Device Description:**

The Cranial IGS System consists of the IGS workstation, the touch screen monitor and the 3D tracking system. A set of hardware accessories provides for comfortable and accurate use of the system.
The IGS workstation holds the patient data during the surgery and runs the cranial software application.
The patient data needed for the image-guided surgery is acquired pre-operatively or intra-operatively and is transferred to the IGS workstation via network, data carrier or data bus.
The cranial software application offers the display of the patient data in various reconstructions, segmentations and overlays on the touch screen in addition to position information of tracked instruments – optionally combined with outlined information. The touch screen enables the control of the cranial software application and can be draped for sterile use by the surgeon.
The electro-magnetic or optical 3D tracking system performs the localization of patient and surgical tools within the operating field.
The virtual diagnostic image spaces are correlated ("registered") to the surgical environment by collecting the 3D position of anatomical landmarks or fiducial markers with a tracked pointer probe and relating them with the corresponding features extracted from the diagnostic image data sets. Alternatively, the patient's skin surface can be scanned with a laser device or touched with a pointer device and matched to the 3D reconstruction of the patient data set. If several diagnostic image spaces have been acquired from the same patient, only one of them has to be registered whereas the remaining ones can be fused to the registered data set.

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Intra-operatively acquired patient data can furthermore be correlated ("registered") to the surgical environment by determining its spatial position in relation to the patient during its acquisition.
Structures in the patient's body are localized using trackable pre-calibrated or intra-operatively calibrated surgical instruments. Examples of surgical instruments are the pointer tool, biopsy needles, catheter stylets or suction tubes.
Surgical microscopes, ultrasound devices and endoscopes are additional intra-operative image sources, which are connected with the Cranial IGS System via signal transmission cables. They can be calibrated and tracked similar as any other surgical instrument. Their images can be displayed on the touch screen or external monitors and combined with the available patient data in correct spatial relation. The settings of microscope and ultrasound devices offering a communication interface can be controlled from the Cranial IGS System. Navigation information can be displayed in the microscope's image injection module.
Defined components of the Cranial IGS System are prepared for the use in magnet-resonance environments.
The Cranial IGS System contains hardware accessories and software features to improve the support and guidance of surgical instruments.
The Cranial IGS System contains a network based software interface that allows downloading medical data (such as image sets, objects, trajectories or points) and tracking data from the system as well as to upload and display an image stream to the system. This interface can be used to implement custom visualization of medical data (e.g. included modalities which are otherwise unknown to the cranial software application) as well as to control other devices. These view data is strictly under the responsibility of the user and clearly marked as such.

Modification:
The added accessory "Disposable Stylet" is designed to be delivered sterile to the customer and for single use only. The instruments reference geometry is included in the instrument design. Only the stylet is packed without e.g. the catheter.
The Disposable Stylet is a pre-calibrated instrument. This means that the software contains calibration information optimized for the Disposable Stylet. Further calibration by the user is not necessary.
To use the Disposable Stylet, it is necessary to load the calibration and verify its accuracy using an ICM (Instrument Calibration Matrix) or a reference array.

3. **Substantial equivalence:**

The added accessory "Disposable Stylet" 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 Cranial Image Guided Surgery System (K082060).

Compatibility of the Disposable Stylet to third-party catheters has been shown in performance testing. Therefore the force necessary to extract the Disposable Stylet vs. third-party stylets out of catheters representing common boundary conditions like materials, coatings and sizes was measured. This had been done in air as well as in saline to simulate the intended use. The validated boundary third party catheter specifications are shown on the Disposable Stylet labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

BrainLab AG
c/o Mr. Alexander Druse
Senior Design Engineer
Kapellenstrasse 12
Feldkirchen
Germany 85622

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Re: K092467
Trade/Device Name: Cranial Image Guided Surgery System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: April 15, 2010
Received: April 26, 2010

Dear Mr. Druse:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092467

Device Name: Cranial Image Guided Surgery System

Indications For Use:

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Ethmoidectomies
Spheno-idotomies/ sphenoid explorations
Turbinate resections
Frontal sinusotomies
Intranasal

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)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K092467