

OCT 19 2004

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

Manufacturer:

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Germany
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Contact Person: Mr. Per Person

Summary Date: October 06, 2004

Device Name:

Trade name: Kolibri™ Image Guided Surgery System (K042391)
Common/Classification Name: Image Guided Surgery System / Instrument, Stereotaxic
Product Code: HAW CFR 882.4560

Predicate Devices:

Kolibri™ Image Guided Surgery System (K014256)

Catheter Introducer for the StealthStation System (K022126)

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

Indications for use:

The BrainLAB Kolibri IGS System is intended to be an intraoperative 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 a patient's preoperative diagnostic image data set being processed by the Kolibri computer 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, X-ray or MR based model of the anatomy.

Example image guided cranial surgery procedures include but are not limited to:

1. Tumor resections
2. Skull base surgery
3. Cranial biopsies
4. Craniotomies/Craniectomies
5. Pediatric Catheter Shunt Placement (New)
6. General Catheter Shunt Placement (New)

Example image guided ENT surgery procedures include, but are not limited to:

1. Transphenoidal procedures
2. Maxillary antrostomies
3. Ethmoidectomies,
4. Sphenoidotomies./sphenoid explorations,
5. Turbinate resections
6. Frontal sinusotomies
7. Intranasal procedures

Device Description:

The Kolibri Image Guidance System is based on a portable hardware platform with integrated touch screen monitor, 3D tracking system controller and computer workstation. The localization of patient position and surgical tools within the operating field will be performed by a magnetic or optical 3D localization system. All patient data needed for the image guided surgery procedure will be transferred via the hospital LAN network or external media (e.g. CD-ROM) to the Kolibri workstation. Once the patient data is transferred to the Kolibri system, the application software automatically starts with the patient registration procedure. The user may perform the patient to 3D data registration either by using anatomical landmarks, fiducial markers or surface matching. The patient registration will be performed by use of a magnetic or optically tracked registration pointer. The surgeon can control all software functions of the Kolibri navigation system via touch screen. Therefore the monitor of the Kolibri navigation system will be draped with a sterile drape during the procedure.

Description of Device Modifications:

This submission extends the Kolibri Image Guided Surgery System functionality with instruments to place catheter shunts. The catheter placement option of the Kolibri system is technically equivalent to the Catheter Introducer for the StealthStation System. All Kolibri systems use either passive reflective markers or electromagnetic coils to track surgical instruments (e.g. the catheter stylet) in relation to reference geometry. This information is correlated to the patient's CT, MR or fluoroscopic images of the anatomy and a preplanned trajectory. This submission provides new indications that are substantially equivalent to the named predicate devices' indication for use.

Substantial equivalence:

The Kolibri™ Image Guides Surgery System (K042391) incl. application software for Cranial and ENT applications 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 Catheter Introducer for the StealthStation System (K022126) and Kolibri Image Guided Surgery System (K014256).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2004

Mr. Jens Witte
BrainLab AG
Ammerthalstrasse 8
85551 Heimstetten,
Germany

Re: K042391
Trade/Device Name: Kolibri Image Guided Surgery System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: August 25, 2004
Received: September 2, 2004

Dear Mr Witte:

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.

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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,

for Miriam C. Provost

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): K042391

Device Name: Kolibri Image Guided Surgery System

Indications For Use:

General description:

The BrainLAB Kolibri IGS System is intended to be an intraoperative 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 a patient's preoperative diagnostic image data set being processed by the Kolibri computer 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, X-ray or MR based model of the anatomy.

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6. Frontal sinusotomies
7. Intranasal procedures

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Miriam C. Provost
(Division Sign-Off)

(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE, RETURN TO THE SUPPLIER PAGE IF NEEDED)

**Division of General Restorative
and Neurological Devices**

Concurrence of CD/RH, Office of Device Evaluation (ODE)

510(k) Number K042391