JUL 19 2002

K014256

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

Manufacturer:

Address: BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany
Phone: +49 89 99 15 68 0
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Contact Person: Mr. Stefan Vilsmeier, President & CEO

Summary Date: July 15, 2002

Device Name:

Trade name:	Kolibri™ Image Guided Surgery System (K014256)
Common/Classification Name:	Image Guided Surgery System / Instrument, Stereotaxic
Product Code:	HAW CFR 882.4560

Predicate Devices:

Medtronic StealthStation® System Goldeneye™ Micro-Magnetic Tracking Option (K001284)

COMPASS Regulus™ Navigator (K964229)

BrainLAB VectorVision (Cranial/ENT/Spinal) (K003589)
BrainLAB VectorVision² (K983831)

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

K014256

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 navigation software won't be installed on the system hard disk but will be delivered on "memory modules that will be externally plugged into the system platform according to the current intended kind of surgery. 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 will be transferred via the hospital LAN network or external media drives 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.

Substantial equivalence:

The Kolibri™ Image Guides Surgery System 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 StealthStation® System Goldeneye™ Micro-Magnetic Tracking (K001284), the Regulus™ Navigator and the BrainLAB VectorVison (Cranial/ENT/Spinal) (K003589) / BrainLAB VectorVision² (K983831).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2002

Mr. Stefan Vilsmeier
BrainLab AG
Ammerthalstrasse 8
Heimstetten
Germany 85551

Re: K014256
Trade/Device Name: Kolibri IGS System
Regulation Number: 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: II
Product Code: HAW
Dated: April 16, 2002
Received: April 24, 2002

Dear Mr. Vilsmeier:

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.

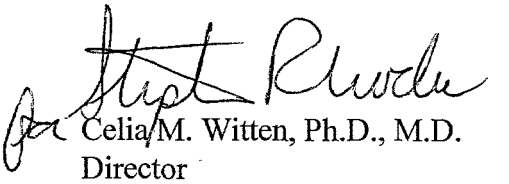
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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): K014256

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

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

510(k) Number K014256