APR 19 2005

K043721

510 (k) Summary of Safety and Effectiveness for Kolibri spine

Manufacturer:

Address: BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany
Phone: +49 89 99 15 68 0
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Contact Person: Mr. Rainer Birkenbach

Summary Date: March 8, 2004

Device Name:

Trade name: Kolibri spine

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

Predicate Device:

BrainLAB VV CT / Fluoro (K010968)
BrainLAB Kolibri™ Image Guided Surgery System (K014256)

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

Intended Use:

BrainLAB's Kolibri spine 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 a patient's preoperative image data being processed by a Kolibri 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, the pelvis, a long bone or vertebra can be identified relative to a CT, X-ray or MR-based model of the anatomy.

Example procedures include but are not limited to:

Spinal implant procedures such as pedicle screw placement
Kyphoplasty and Vertebroplasty procedures
Placement of other temporary or permanent devices such as k-wires, needles, catheters or electrodes
Thoracic spine surgery
Tumor surgery on the spinal column and adjacent soft tissue
Placement of acetabular and SI screws on the pelvis

Device Description:

Kolibri spine is a device that allows surgical planning and navigation. It links a surgical instrument, (tracked by passive marker sensor system) to a location on a virtual computer image, which is either based on patient's preoperative 3D information of a CT or MR dataset or based on patient's intraoperative acquired 2D fluoro image(s) of a c-arm.

The device enables the navigation based on 3D data and/or based on acquired fluoro images (Fluoro only).

Based on 3D data, the procedure of linking the surgical instrument to the virtual computer image is achieved by performing certain registration methods.

Based on 2D fluoro images, the registration is done automatically by using the exact spatial position information of the intra-operatively acquired fluoro images.

After registration, the device assists the surgeon in performing certain surgical procedures as described in the indications for use.

Substantial equivalence:
Kolibri spine 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 BrainLAB VV CT / Fluoro (K010968) and BrainLAB Kolibri™ Image Guided Surgery System (K014256)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 2005

Mr. Per Persson
Quality Manager
BrainLab AG
Ammerthalstraße 8
85551 Heimstetten, Germany

Re: K042721
Trade/Device Name: Kolibri spine
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: March 18, 2005
Received: March 21, 2005

Dear Mr. Persson:

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 (240) 276-0120 . 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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K042721

Device Name: Kolibri spine

Indications For Use:

BrainLAB's Kolibri spine 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 a patient's preoperative image data being processed by a Kolibri 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, the pelvis, 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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Thoracic spine surgery
Tumor surgery on the spinal column and adjacent soft tissue
Placement of acetabular and SI screws on the pelvis

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)

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K042721