JUN - 6 2006

K053159

510 (k) Summary of Safety and Effectiveness for VectorVision 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: September 13, 2005

Device Name:

Trade name: VectorVision spine

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

Predicate Device:

BrainLAB VectorVision CT / Fluoro (K010968)
BrainLAB Kolibri spine (K042721)

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

Intended Use:

BrainLAB's VectorVision spine is intended for use as an intraoperative image-guided localization system for 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 that is processed by a 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, 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:

- Navigated spinal procedures in support of standard approaches (e.g. anterior, lateral, oblique)
- Spinal implant procedures such as
    - Pedicle screw placement
    - Anterior plating
- 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:

VectorVision 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.

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

Based on 3D data, the procedure of linking the surgical instrument to the virtual computer image is achieved by performing registration methods as paired point matching, surface matching, region matching or CT fluoro matching. The last registration method uses 2D fluoro images to register the previously acquired 3D dataset. Thus, CT fluoro matching combines 2D fluoro imaging with 3D datasets.

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

Substantial equivalence:
VectorVision 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 VectorVision CT / Fluoro (K010968) and BrainLAB Kolibri spine (K042721).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

BrainLAB AG
% Mr. Martin Ringholz
Project Engineer IGS Spine
Ammerthalstrasse 8
Heimstetten, Germany 85551

Re: K053159
Trade/Device Name: Vector Vision spine
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulation Class: II
Product Code: HAW
Dated: May 23, 2006
Received: May 25, 2006

Dear Mr. Ringholz:

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.

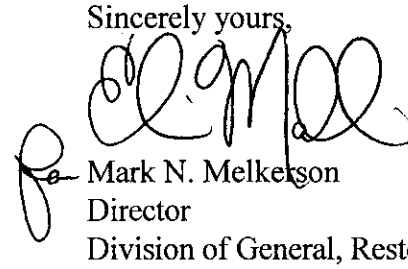
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K053159

Indications for Use

510(k) Number (if known): K053159

Device Name: Vector Vision spine

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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 General, Restorative, and Neurological Devices

510(k) Number K053159