K070106

APR 23 2007

510 (k) Summary of Safety and Effectiveness for VectorVision fluoro 3D

Manufacturer:

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Germany
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Contact Person: Mr. Per Persson

Summary Date: April 18, 2007

Device Name:

Trade name: VectorVision fluoro 3D

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

Predicate Device:

VectorVision fluoro 3D (K024192)
VectorVision spine (K053159).

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

Intended Use:
BrainLAB VectorVision fluoro3D is intended as 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 or Intraoperative 2D or 3D image data.
VectorVision fluoro3D enables computer-assisted navigation of medical image data, which can either be acquired preoperatively or intraoperatively by an appropriate image acquisition system.
The software offers screw implant size planning and navigation on rigid bone structures with precalibrated and additional individually-calibrated surgical tools.
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 the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.

Device Description:

VectorVision fluoro 3D 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 intraoperative 3D information acquired with a 3D C-arm or based on patient's intraoperative acquired 2D fluoro image(s) of an analog or digital 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 information of the intra-operatively acquired fluoro images.
Based on 3D data, the registration is also done automatically by using the exact spatial position information of the start position of the scan. Beforehand, the 3D Siemens C-arm has to be calibrated in combination with the navigation system.
For 3D data, the paired point matching and the 2D 3D fluoro matching are also available as reregistration methods. The last registration method uses two fluoro images (one in AP and one in lateral position) to regain accuracy on previously acquired 3D scans. This may become necessary if the reference on the patients bone has become lose.

The device assists the surgeon in performing certain surgical procedures as described in the indications for use.

Substantial equivalence:
VectorVision fluoro 3D 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 fluoro 3D version 1.0 (K024192) and BrainLAB VectorVision spine version 5.5.1 (K053159).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2007

BrainLAB AG
% Mr. Per Persson
Manager Regulatory Affairs
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85622 Feldkirchen
Germany

Re: K070106
Trade/Device Name: Vector Vision fluoro 3D
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: January 3, 2007
Received: February 5, 2007

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) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number (if known): K070106

Device Name: Vector Vision fluoro 3D

Indications For Use:

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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 K070106