K062358

510 (k) Summary of Safety and Effectiveness for VectorVision trauma

Manufacturer:

Address: BrainLAB AG
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Germany
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JAN 17 2007

Contact Person: Mr. Rainer Birkenbach

Summary Date: August 10, 2006

Device Name:

Trade name: VectorVision trauma

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

Predicate Device:
Vector Vision trauma (K 012448)

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

Intended Use:
BrainLAB VectorVision trauma is intended to be a pre- and 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 pre- or intraoperative image data being 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, a bone structure like tubular bones, pelvic, calcaneus and talus, or vertebra, can be identified relative to a CT, fluoroscopic, X-ray or MR based model of the anatomy.

Example procedures include but are not limited to:
Spinal procedures and spinal implant procedures such as pedicle screw placement.
Pelvis and acetabular fracture treatment such as screw placement or ilio-sacral screw fixation.
Fracture treatment procedures, such as intramedullary nailing or plating or screwing or external fixation procedures in the tubular bones.

Device Description:
BrainLAB VectorVision trauma is intended to enable operational navigation in spinal, orthopedic and traumatologic surgery. It links a surgical instrument, tracked by flexible passive markers to virtual computer image space on a patient's intraoperative image data being processed by a VectorVision workstation.

VectorVision trauma allows navigation of intraoperatively acquired images considering patient's movement in correlation to calibrated surgical instruments. This allows implant positioning, screw placement and bone reduction in different views and reduces the need for treatments under permanent fluoroscopic radiation.

Substantial equivalence:
VectorVision trauma 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 VectorVision trauma (K012448).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BrainLAB AG
% Rainer Birkenbach
Executive Vice President
Kapellenstrasse 12
85662 Feldkirchen
Germany

JAN 17 2007

Re: K062358
Trade/Device Name: VectorVision trauma
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: December 26, 2006
Received: December 26, 2006

Dear Rainer Birkenbach:

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

K062358

Indications for Use

510(k) Number (if known):

Device Name: VectorVision trauma

Indications For Use:

BrainLAB VectorVision Trauma is intended to be a pre- and 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 pre- or intraoperative image data being 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, a bone structure like tubular bones, pelvic, calcaneus and talus, or vertebra, can be identified relative to a CT, fluoroscopic, X-ray or MR based model of the anatomy.

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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 K062358