K093117

510 (k) Summary of Safety and Effectiveness for Digital Lightbox

DEC 11 2009

Manufacturer:

Address: BrainLAB AG
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Contact Person: Mr. Alexander Schwiersch

FDA CDRH DMC

Summary Date: November 19, 2009

DEC 03 2009

Received

Device Name:

Trade name:	Digital Lightbox
Common/Classification Name:	Digital Lightbox, BrainLAB system, image processing, radiological
Product Code:	LLZ
Regulation Number	21 CRF §892.2050

Predicate Devices:

iPlan (K053127)
- Product Code: HAW
- Regulation Number: 21 CFR 882.4560

Digital Lightbox (K080608)
- Product Code: LLZ
- Regulation Number: 21 CRF §892.2050

Device Classification Name: System, image processing, radiological
Regulatory Class: Class II

Intended Use:

The Digital Lightbox is a system intended for the display of medical images. The software can transfer images to and from picture archiving and communication systems (PACS), file servers, or removable storage media. It includes functions for image manipulation, basic measurements and 3D visualization (reconstructions and volume rendering). Features for navigation planning include multi-modality image fusion as well as object and trajectory creation. It is not intended for primary image diagnosis or the review of mammographic images.

Device Description:
Digital Lightbox is a medical image viewing device consisting of two high-resolution monitors controlled through touch panels with an integrated PC. It features an Ethernet connection for retrieving medical images through a computer network. Further, the device can read images from CD, DVD or USB drives through external interfaces. The device software is compatible with the DICOM standard and allows basic image manipulation, 3D visualization (reconstructions and volume rendering), basic measurements, multi-modality image fusion and object and trajectory creation. Basic treatment plans can be exported to BrainLAB navigation systems. The device software integrates a web browser and remote access software.

Substantial equivalence:
Digital Lightbox has been verified and validated according to BrainLAB 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 devices iPlan (K053127) and Digital Lightbox (K080608).

Technical Characteristics:
The technical characteristics are equivalent to the predicate device Digital Lightbox (K080608), except for the new functionality 3D visualization and basic surgical planning including object and trajectory creation and plan export to navigation systems. This new functionality is equivalent to the corresponding features in the predicate device iPlan (K053127).
The Digital Lightbox conforms to the DICOM standard.

Documentation:
The reason for this submission is a change in intended use of the previously submitted Digital Lightbox (K080608). This 510(k) submission contains documentation only for features in the product Digital Lightbox that were not included in the previously submitted Digital Lightbox (K080608).

The risk analysis contains only risks identified due to the changes in software and intended use. Further, as all changes apply to software only, this submission contains documentation of the software only. The Digital Lightbox hardware is unchanged and is not affected by the changes in intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC 11 2009

Mr. Alexander Schwiersch
Regulatory Affairs Manager
BrainLAB AG
Kapellenstrasse 12
Feldkirchen, 85622
GERMANY

Re: K093117
Trade/Device Name: Digital Lightbox
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 27, 2009
Received: December 3, 2009

Dear Mr. Schwiersch:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093117

Device Name: Digital Lightbox

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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)

Colin A Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093117