K080608

APR 17 2008

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

Manufacturer:

Address: BrainLAB AG
Kapellenstrasse 12
85622 Feldkirchen
Germany
Phone: +49 89 99 15 68 0
Fax: +49 89 99 15 68 33

Contact Person: Mr. Per Persson

Summary Date: November 13, 2007

Device Name:

Trade name: Digital Lightbox

Common/Classification Name: Digital Lightbox, BrainLAB system, image processing, radiological

Predicate Devices:

iPlan (K 053127)
iPlan Hip Templating (K 042543)
DGSCOPE, RELEASE 1.0 (K 070397)

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

Intended Use:

The Digital Lightbox is a system intended for the retrieval and display of medical images from picture archiving and communication systems (PACS), file servers, or removable storage media. It includes functions for image manipulation, 3D reconstruction, basic measurements, and multi-modality image fusion. 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 reconstruction, basic measurements and multi-modality image fusion. 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 (K 053127), iPlan Hip Templating (K 042543) and DGSCOPE, RELEASE 1.0 (K 070397).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2008

Mr. Rainer Birkenbach
Executive Vice President
BrainLAB AG
Kapellenstraße 12
85622 Feldkirchen
GERMANY

Re: K080608
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: February 22, 2008
Received: March 4, 2008

Dear Mr. 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Nancy C Brogdon

Nancy C. Brogdon
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):

Device Name: Digital Lightbox

Indications For Use:

The Digital Lightbox is a system intended for the retrieval and display of medical images from picture archiving and communication systems (PACS), file servers, or removable storage media. It includes functions for image manipulation, 3D reconstruction, basic measurements, and multi-modality image fusion. It is not intended for primary image diagnosis or the review of mammographic images.

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 Reproductive, Abdominal and Radiological Devices
510(k) Number K080608