DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 13, 2016

Brainlab AG
% Mr. Alexander Schwiersch
Regulatory Affairs Manager
Kapellenstrasse 12
Feldkirchen 85622
GERMANY

Re: K153653
Trade/Device Name: DICOM Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 2, 2016
Received: March 7, 2016

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153653

Device Name

DICOM Viewer

Indications for Use *(Describe)*

DICOM Viewer is a software device for display of medical images and other healthcare data. It includes functions for image review, image manipulation, basic measurements and 3D visualization (MPR reconstructions and 3D volume rendering).
It is not intended for primary image diagnosis or the review of mammographic images.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510 (K) SUMMARY
DICOM VIEWER

IN ACCORDANCE WITH REQUIREMENTS OF 21 CFR PART 807.92

Manufacturer:	Brainlab AG Kapellenstrasse 12 85622 Feldkirchen Germany Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 33
Submitter:	Rainer Birkenbach
Contact person:	Alexander Schwiersch
Summary date:	11/5/2015
Device:	Image Viewer
Trade name:	DICOM Viewer
Device Classification Regulation:	892.2050 - Picture archiving and communications system
Regulatory Class:	Class II
Product Code:	LLZ – System, Image Processing, Radiological
Main Predicate Device:	Digital Lightbox (K093117)
Secondary Predicate Device:	CONi (K130624)

1 INTENDED USE:

DICOM Viewer is a software device for display of medical images and other healthcare data. It includes functions for image review, image manipulation, basic measurements and 3D visualization (MPR reconstructions and 3D volume rendering).

It is not intended for primary image diagnosis or the review of mammographic images.

2 DEVICE DESCRIPTION:

The DICOM Viewer is software for web based viewing of DICOM data.

Operator profile

The device is generally used by medical professionals such as doctors, their assistants or nursing staff which are in need of displaying medical (DICOM) images and other healthcare data for non-diagnostic purposes.

Patient population

The device is software which allows viewing of DICOM data. Hence there is no specific patient population.

Intended use environment

The software is intended to be used:

- in Operating Rooms
- in Office environments within hospitals or at any other location offering a computer
- at any location on tablet devices

Operating principle

There are different operating principles:

- On desktop PCs the interaction with the software is mainly performed with mouse and/or keyboard
- On touch screen PCs and on mobile devices the software is mainly used with a touch screen interface.

Primary operating functions

Non-diagnostic viewing of medical images and other healthcare data in DICOM format.

Use scenarios

- A user wants to review DICOM data in an OR before or during a surgery in order to think about the procedure or to talk about the procedure with his colleagues.
- A user wants to review DICOM data of patients in a regular board meeting in order to discuss aspects of treatments with his colleagues
- A user wants to review DICOM data of patients in a meeting where the participants are not in the same room in order to discuss aspects of treatments with his colleagues or to get the opinion of an external expert

Intended part of the body or type of tissue applied to or interacted with

The device is software only which allows viewing of DICOM data. Hence it does not interact with any body/tissue part and the viewing is not limited to any body/tissue part.

Essential performance characteristics

Image Viewer is essentially software for medical image visualization. A hardware shutdown, power failure or other hardware issue that makes the software inoperable does not cause harm. Hence, no unacceptable risk arises if the hardware loses performance. Therefore, the hardware does not have any essential performance characteristics.
The software risks were analyzed to find risks in the non-acceptable area. No risks have been identified in the non-acceptable area. Hence, no measures are considered essential performance characteristics.
In summary, the Image Viewer software does not have any essential performance characteristics.

3 SUBSTANTIAL EQUIVALENCE

DICOM Viewer has similar functionality, intended use, technological characteristics, and typical users as

the predicate devices.

Both DICOM Viewer and the primary predicate device, Digital Lightbox (K093117) are used to display medical images including multiplanar reconstructions and 3D volume rendering, perform basic image manipulations and measurements, and load and visualize planning data as fusions, objects and trajectories. Both devices are Brainlab products, have been developed by the same R&D team and use the same software framework. Both DICOM Viewer and all two predicate devices (Digital Lightbox (K093117) and CONi (K130624)) are intended to view medical images.

In contrast to the primary predicate device, Digital Lightbox (K093117), the DICOM Viewer has a web frontend which is available on multiple devices (computers, Android tablets and iPads); whereas, the Digital Lightbox is accessible and running on a dedicated system only. However the other predicate device CONi (K130624) is also web-based software for viewing DICOM Images.

In addition the DICOM Viewer can display fiber objects generated by other Brainlab applications and align images sets and persist the align state. These enhancements in respect to the predicate devices do not affect the intended use, alter the fundamental technology of the primary predicate device, Digital Lightbox (K093117) nor do they introduce any new issues concerning safety and effectiveness.

4 VERIFICATION/VALIDATION SUMMARY

Verification

The verification of the System DICOM Viewer has been carried out thoroughly both at the top level and on underlying modules. The verification was done to demonstrate that the design specifications are met.

Non-clinical validation

- DICOM Viewer 2.2 and DICOM Viewer 3.0 are substantially equivalent regarding user group, use scenario, use related risks and the user interface being nearly identical. Thus safe use of the device can be posed on post-market evaluation for the DICOM Viewer 2.2.
- Validation contained reviews of the MAUDE, BfArM and Brainlab internal complaint databases regarding incidents of similar products including the DICOM Viewer 2.2. The search results did not result in any necessary actions for the DICOM Viewer.
- The validation of the intended use, user needs and primary operating functions of the DICOM Viewer 3.0 is additionally covered by specific sections in the verification protocols.
- Formative usability tests have been performed as listed in the Usability Evaluation Summary. The prototype is substantially equivalent with the user interface being nearly identical to the final device. Only bug fixes and minor improvements of the software with no effect on the results of the formative usability tests have been incorporated afterwards.

5 CONCLUSION

The comparison of the DICOM Viewer with the predicate devices using available labelling (Digital Lightbox K093117 and CONi K130624) and Brainlab internal specifications (Digital Lightbox K093117) shows that the DICOM Viewer has similar functionality, intended use, technological characteristics, and typical users as the predicate devices. Verification and validation activities ensure that the design specifications are met and that the DICOM Viewer does not introduce new issues concerning safety and effectiveness. Hence DICOM Viewer is substantial equivalent to the predicate devices.