Brainlab AG
% Chiara Cunico
Manager Regulatory Affairs
Olof-Palme-Str. 9
81829 Munich, De
GERMANY

January 23, 2020

Re: K191014
Trade/Device Name: Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 16, 2019
Received: December 26, 2019

Dear Chiara Cunico:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191014

Device Name
Viewer

Indications for Use *(Describe)*
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 (Multiplanar 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510 (K) SUMMARY
VIEWER

IN ACCORDANCE WITH REQUIREMENTS OF 21 CFR PART 807.92

General Information	
Manufacturer	Brainlab AG, Olof-Palme-Straße 9, 81829 Munich, Germany
Establishment Reg. #	8043933
Device name:	Viewer
Trade name:	Elements Viewer
Common name	DICOM Viewer
Classification name:	Picture archiving and communications system (21 CFR 892.2050)
Review Panel	Radiology
Product Code:	LLZ
Device Class:	Class II
Predicate Device:	K153653 DICOM Viewer
Reference Device	K172418 OpenSight
Date of preparation	23 September 2019

Contact Information	
Primary contact person	**Alternate contact person**
Chiara Cunico Manager RA phone: +49 89 99 15 68 1738 Email: Chiara.cunico@brainlab.com	Regulatory Affairs Brainlab phone: +49 89 99 15 68 0 fax: +49 89 99 15 68 5033 Email: regulatory.affairs@brainlab.com

Intended use: 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 (Multiplanar reconstructions and 3D volume rendering).
It is not intended for primary image diagnosis or the review of mammographic images.

Device description

Viewer is a software for viewing of DICOM data. The device provides basic measurement functionality for distances and angles.
These are the 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.
- On Mixed Reality glasses the interaction is performed with a dedicated pointing device.

The subject device provides or integrates the following frequently used functions:

- Select medical images and other healthcare data to be displayed
- Select views (e.g. axial, coronal & sagittal reconstruction views and 3D volume rendering views)
- Change view layout (e.g. maximize / minimize views, close / open / reorder views)
- Manipulate views (e.g. scroll, zoom, pan, change windowing)
- Perform measurements (e.g. distance or angle measurements)
- Place annotations at points of interests

Changes to Predicate Device

Convenience function have been added for view and object selection.

Magic Leap Mixed reality glasses have been added to the Subject Device as additional means of display. The Mixed Reality views are started from within the desktop version of Viewer. The view selection is done on the desktop, the views are cloned into the virtual space of Mixed Reality. The 2D views are shown on a 2D view pane in Mixed Reality. The 3D views are placed as virtual objects in to the real world.

Technological Characteristics of the Subject Device in comparison to the Predicate Device

	Cleared device feature/specification **DICOM Viewer (K153653)**	Modified device feature/specification **Viewer 5.0**	Substantial Equivalent
HW Environment	Server based, for viewing via HTML5 client or RDP on individual client computer	Server and local installation, , for viewing via HTML5 client or RDP, or local execution on individual client computer	yes
Data inputs	DICOM		yes
Viewing Data	• Skin • Bone • Skin/Bone • Vessels • Bone/Vessels • Skin/Vessels • Skin/Bone/Vessels • Maximum Intensity Projection (MIP) • Digital Reconstructed Radiograph (DRR)		yes

	Cleared device feature/specification **DICOM Viewer (K153653)**	Modified device feature/specification **Viewer 5.0**	Substantial Equivalent
Measurement	• Distance in slice sets • Diameter • Angle	• Distance in slice sets and X-ray images • Diameter • Angle (incl. open angle)	yes
"Smart View"	Individual selectable visibility of objects (tumor, fibers etc.)	Individual selectable visibility of objects (tumor, fibers etc.) **Additional** view: with a slider it is possible to change visibility of objects.	yes
View Layouts	Manual selection of appropriate view.	Manual selection of appropriate view. **Additional**: Cranial, Spine and Angio layouts load views in the presence of certain modalities in the Subject Device.	yes
Probe's Eye View (available in Mixed Reality)	Align crop box to any desired direction for the display of MPR perpendicular and parallel (inline) to the given direction.	Align crop box to any desired direction for the display of MPR perpendicular and parallel (inline) to the given direction. In Mixed Reality the user can point in a desired direction and view MPR perpendicular and parallel (inline) to the given direction.	yes

Technological Characteristics of the Subject Device in comparison to the Reference Device:

	Cleared device feature/specification **OpenSight K172418**	Modified device feature/specification **Viewer 5.0**	Substantial Equivalent
Supported Mixed Reality Device	Microsoft HoloLens	Magic Leap One	yes
Supported device electrical medical device according to IEC 60601-1	No	No	yes
Mixed Reality	2D slices and MPRs 3D Views	2D slices and MPRs 3D Views	yes
Registration to patient	yes	no	No, this is not part of the Subject Device. Equivalence is not claimed

Verification summary:

Verification of communication and cybersecurity between Viewer and Magic Leap Mixed Reality glasses has been tested. All interactive testing of user interface have successfully passed.

Validation summary:

The validation comprises usability tests which ensure that the user interface can be used safely and effectively. All tests were rated as successfully passed according to their acceptance criteria.

As conclusion, the nonclinical and clinical tests (discussed above) demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

Test	Test Method Summary	Results
User interface	Interactive testing of user interface	All tests passed
DICOM compatibility	Interactive testing with companywide test data, which are identical for consecutive version of the SW	All tests passed
Views	Interactive testing of user interface	All tests passed
Unit test /Automatic tests	Automated or semi-automated cucumber tests or unit tests are written on the applicable level for new functionalities of the Viewer in respect to previous versions. Exiting tests have to pass.	All tests passed

Test	Test Method Summary	Results
Integration test	Interactive testing on various platforms and combination with other products following test protocols, combined with explorative testing. The software is developed with daily builds, which are explanatively tested.	All tests passed

Substantial equivalence

The comparison of the Viewer with the predicate device shows that the Viewer has similar functionality, intended use, technological characteristics, and typical users as the predicate device. Verification and validation activities ensure that the design specifications are met and that the Viewer does not introduce new issues concerning safety and effectiveness. Hence the Viewer is substantial equivalent to the predicate device.