October 16, 2025

Brainlab AG
Sadwini Suresh
QM Consultant
Olof-Palme-Str. 9
Munich, 81829
Germany

Re: K252476
Trade/Device Name: Viewer (5.4); Elements Viewer; Mixed Reality Viewer; Smart Layout; Elements Viewer Smart Layout
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 24, 2025
Received: September 24, 2025

Dear Sadwini Suresh:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252476

Please provide the device trade name(s).

Viewer (5.4);
Elements Viewer;
Mixed Reality Viewer;
Smart Layout ;
Elements Viewer Smart Layout

Please provide your Indications for Use below.

The software displays medical images and data. It also includes functions for image review, image manipulation, basic measurements and 3D visualization.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

OCTOBER 13, 2025

General Information

Manufacturer	Brainlab AG; Olof-Palme-Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Trade Name	Viewer 5.4; Elements Viewer; Mixed Reality Viewer; Smart Layout ; Elements Viewer Smart Layout
Classification Name	System, Image Processing, Radiological
Product Code	LLZ
Regulation Number	892.2050
Regulatory Class	II
Panel	Radiology
Predicate Device(s)	Viewer 5.4; K232759

Contact Information

Primary Contact	Alternate Contact
Sadwini Suresh QM Consultant – Regulatory Affairs Phone: +49 89 99 15 68 0 Email: regulatory.affairs@brainlab.com	Chiara Cunico Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 5033 Email: chiara.cunico@brainlab.com

1. Indications for Use

   The software displays medical images and data. It also includes functions for image review, image manipulation, basic measurements and 3D visualization.

2. Device Description

   Viewer is a software for viewing DICOM data, such as native slices generated with medical imaging devices, axial, coronal and sagittal reconstructions, and data specific volume rendered views (e.g., skin, vessels, bone). Viewer supports basic manipulation such as windowing, reconstructions or alignment and it provides basic measurement functionality for distances and angles. Viewer is not intended for diagnosis nor for treatment planning. The Subject Device (Viewer) for which we are seeking clearance consists of the following software modules.
   • Viewer 5.4.2 (General Viewing)
   • Universal Atlas Performer 6.0
   • Universal Atlas Transfer Performer 6.0

Universal Atlas Performer: Software for analyzing and processing medical image data with Universal Atlas to create different output results for further use by Brainlab applications

Universal Atlas Transfer Performer: Software that provides medical image data auto-segmentation information to Brainlab applications

When installed on a server, Viewer can be used on mobile devices like tablets. No specific application or user interface is provided for mobile devices. In mixed reality, the data and the views are selected and opened via desktop PC. The views are then “cloned” into the virtual image space of connected mixed reality glasses. Multiple users in the same room can connect to the Viewer session and view/review the data (such as already saved surgical plans) on their mixed reality glasses.

3. Substantial Equivalence

For the Substantial Equivalence determination, comparison of the Subject Device features with the following predicate device(s) was carried out:

Viewer 5.4; K232759

There are no major changes between the subject device and the predicate.

Feature	Predicate Device	Subject Device
Indications for use	The software displays medical images and data. It also includes functions for image review, image manipulation, basic measurements and 3D visualization.	The software displays medical images and data. It also includes functions for image review, image manipulation, basic measurements and 3D visualization. The device itself does not have clinical indications.
Computer hardware requirements	- Graphics: DirectX 11 compatible with 512 MB graphics memory - Display resolution: 1280x1024 - Processor: 4 physical cores - RAM: 4GB, 8GB for 3D Stereo - With a mouse or touchscreen as pointing device	- Graphics: DirectX 11 compatible with 512 MB graphics memory - Display resolution: 1280x1024 - Processor: 4 physical cores - RAM: 4GB, 8GB for 3D Stereo - With a mouse or touchscreen as pointing device

Feature	Predicate Device	Subject Device
Mixed Reality Glasses	Magic Leap 2 IT version	Magic Leap 2 medtech and IT version
Operating System	Windows Server 2012, 2016, 2019 min Windows 10 MacOS	Windows Server 2012, 2016, 2019 min Windows 10 MacOS
Buzz Virtual Viewer Remote Control	The views streamed to Buzz Virtual from Viewer, can be interacted through mobile devices with a special layout. This remote control layout consists of predefined essentials tools: • Scroll • Switch • Pan • Rotate • Zoom • Scroll • Windowing • reset	The views streamed to Buzz Virtual from Viewer, can be interacted through mobile devices with a special layout. This remote control layout consists of predefined essentials tools: • Scroll • Switch • Pan • Rotate • Zoom • Scroll • Windowing • reset
Mixed Reality Segmented Dimming	The background of the 2D area Mixed Reality scene is displayed in real black (instead of dark transparent) in Mixed Reality, depending on distance between user and 2D area.	The background of the 2D area Mixed Reality scene is displayed in real black (instead of dark transparent) in Mixed Reality, depending on distance between user and 2D area.
Distance Display	Distance measurements can be set and displayed on 2D Slices on desktop viewer and also on 3D mixed reality views. Moreover, 3D distance measurements can be displayed over multiple 2D views.	Distance measurements can be set and displayed on 2D Slices on desktop viewer and also on 3D mixed reality views. Moreover, 3D distance measurements can be displayed over multiple 2D views.
Origin Data Management (component)	Origin Data Management 3.1 and 3.2 versions compatible to Viewer 5.4.0 include Universal Atlas and UA Transfer	Origin Data Management 3.1 and 3.2 compatible to Image Viewer 5.4.2 include the medical device components Universal Atlas and

Feature	Predicate Device	Subject Device
	Performers 6.0.0 as components. Additionally, they include the medical device component DICOM Proxy 5.0.0 and 5.1.0, respectively.	UA Transfer 6.0.1. Additionally, Origin Data Management 3.1 and 3.2 include the updated medical device component DICOM Proxy 5.1.1. In DICOM Proxy 5.1.1, bugs related to patient data merges were fixed.

4. Performance Data

   a. Software Verification and Validation Testing

      Software verification and validation testing has been conducted and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Device Software Functions". These include successful implementation of product specifications, incremental testing for different release candidates, testing of risk control measures, compatibility testing or cybersecurity tests. The documentation submitted is for enhanced level.

   b. Bench Tests

      The following performance bench tests were carried out:

      Ambient Light Test: To determine the Magic Leap 2 display quality for sufficient visualization in a variety of ambient lighting conditions

      Hospital Environment Tests: To test compatibility of the Subject Device with various hardware platforms and compatible software's.

   c. Display Quality Tests

      Tests were carried out to measure and compare the optical transmittance, and luminance non-uniformity and Michelson contrast of the head mounted display to ensure seamless integration of real and virtual content, and maintenance of high visibility and image quality. The tests were carried out with and without segmented dimming.

   d. Measurement accuracy test

      Additionally, tests were performed to evaluate the accuracy of 3D measurement placement using a Mixed Reality user interface, specifically Magic Leap controller in relation to mouse and touch on desktop as input methods. The accuracy of each input method was compared. The accuracy of each input method was compared. The test was concluded to be passed when inexperienced test persons (3) were able

to place distance measurements with an maximal deviation of less than one millimeter in each axis compared to the other tested input methods.

5. Conclusion

The comparison of the Subject Device with the predicate device shows that the Viewer 5.4 has similar functionality, intended use and technological characteristics as the predicate devices. Based on the comparison to the predicate and the performance testing conducted, the Subject Device is considered substantially equivalent to the predicate device.