Brainlab AG
% Mr. Alexander Schwiersch
Regulatory Affairs Manager
Olof-Palme-Str. 9
München, 81829
GERMANY

April 25, 2019

Re: K190042
Trade/Device Name: Brainlab Elements Image Fusion Angio
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, JAK
Dated: March 22, 2019
Received: March 28, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia T. Mills, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190042

Device Name
Brainlab Elements Image Fusion Angio

Indications for Use *(Describe)*

The application can be used in clinical workflows that benefit from the co-registration of vascular image data as a planning or preplanning step.

There are no demographic, regional or cultural limitations for patients.

The system shall be used in a hospital office environment or rooms appropriate for surgical interventions.

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.

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510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS FOR IMAGE FUSION ANGIO

In accordance with requirements of 21 CFR Part 807.92

Manufacturer:	Brainlab AG Olof-Palme-Str. 9 81829 Munich Germany Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 5033
Submitter:	Rainer Birkenbach
Contact person:	Alexander Schwiersch
Summary date:	12/21/2018
Device:	Image Fusion Angio
Trade name:	Brainlab Elements Image Fusion Angio
Common/Classification Name:	System, Image Processing, Radiological
Predicate Device:	Image Fusion (K170816)
Reference Device:	iPlan RT Image (K080886)
Device classification name:	Picture archiving and communications system
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
Intended use:	Image Fusion Angio 1.0 is a software application that is intended to be used for the co-registration of cerebrovascular image data.

Indications for use:	The application can be used in clinical workflows that benefit from the co-registration of vascular image data as a planning or preplanning step.
Device description:	Image Fusion Angio is intended to co-register digital subtraction angiographies with volumetric medical image data.
Operator Profile:	The application is intended to be used by medical professionals and their assistants working in the field of neurosurgery, neuroradiology or radiotherapy planning.
Patient Population:	There are no demographic, regional or cultural limitations for patients.
Conditions of Use:	The system shall be used in a hospital office environment or rooms appropriate for surgical interventions.
Reason for 510(k) submission:	New device.
Substantial equivalence:	Image Fusion Angio 1.0 (Subject Device) is part of a new software generation at Brainlab. The functionality of the Subject Device has been previously included in the Predicate Device. The Subject Device specifically takes over the fusion algorithm and the GUI design from the predicate device (Image Fusion, K170816). It takes over the ability to load 2D images and fuse them to 3D images from the reference device (iPlan RT Image, K080886). All devices provide the functionality co-register anatomical structures of image data and can be used in planning workflows to treat cranial lesions.
Conclusion:	Functionality and features considered as substantially equivalent have been verified and validated. The system Image Fusion Angio with its set of functionalities is substantially equivalent to its predicate and reference devices.
Changes to Predicate Device:	The new Image Fusion Angio 1.0 Element enlarges the portfolio of already cleared Brainlab Elements. Central changes compared to the main predicate device Image Fusion are based in focusing on image fusion functionality in general.

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

	Cleared device feature/specifications **Image Fusion 3.0** (K170816)	Modified device feature/specifications **Image Fusion Angio 1.0**
HW Requirements and Operating Systems	Equivalent	
Data Inputs	Equivalent	
Viewing Data	Equivalent	
Performing an Image Fusion	Equivalent as follows: The predicate provides identical functions compared to the subject device except for the ability to load 2D images and to co-register them to 3D images. This is not critical for equivalence rating, since this is a known and existing feature.	
Fusion Algorithm	Equivalent as follows: The predicate provides the same algorithm compared to the subject device except for the ability to fuse 3D to 2D images. This is not critical for equivalence rating, since this is a known and existing feature.	
Fusion and Verification Tools	Equivalent	
Accepting a Fusion Result	Equivalent	
Performing a manual fusion	Equivalent	
Choosing a Region of Interest	Equivalent	
Edit and Select Pairs	Equivalent	

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

	Cleared device feature/specifications **iPlan RT Image** (K080886)	Modified device feature/specifications **Image Fusion Angio 1.0**
Fusion Algorithm	Equivalent as follows: The reference device provides functionality for a 2D/3D co-registration in an equivalent context but uses a differing algorithm with respect to the 2D/3D co-registration. This is not critical for equivalence rating, since the resulting co-registration accuracy is equally good, as proven by verification and validation.	

Verification/validation summary:

Verification
Verification has been performed according to the Verification Plan and following internal processes to demonstrate that design specifications are met by the device.

Validation
Validation of the functionalities, including nonclinical performance tests (accuracy tests, see below), has been performed in accordance with the Clinical Evaluation Plan and following internal processes.
Usability tests have been performed as well to ensure that the device can be used safely and that measures against potential use related risks are effective.
The validation has been performed with software and units that are considered equivalent to the final version of the product (in terms of functionality and user interface), as demanded by 21 CFR 820.30 (g).

Nonclinical performance testing (Accuracy)
To evaluate the accuracy of the 2D/3D co-registration we took the following pathway (detailed results see table below):

- **Phantom Bench Test** – to compare the 2D/3D fusion accuracy of CTA, 3D-DSA to 2D-DSA of the Subject Device to the Reference Device.
- **MRA Bench Test** – to compare the 2D/3D fusion accuracy of MRA to 2D-DSA of the Subject Device to the Reference Device.
- **Retrospective Study** – to confirm similar accuracy as shown in the Phantom Bench Test.

Due to the results of the nonclinical tests we demonstrated that the device is as safe, as effective and performs as well as the reference device

Test	Test Method Summary	Results
Phantom Bench Test	We performed 2D and 3D scans using a physical vessel phantom. 2D and 3D images were fused with Image Fusion Angio and iPlan RT Image (reference device). Targeting accuracies of both devices to a gold standard fusion were compared to each other (Euclidean Distances between predefined landmarks). The test was repeated 3 times.	Targeting accuracy, Image Fusion Angio: 0.5 mm +/- 0.2 mm Targeting accuracy, iPlan RT Image: 0.8 mm +/- 0.3 mm
MRA Bench Test	We performed 2D and 3D scans using a retrospective patient data set. 2D and 3D images were fused with Image Fusion Angio and iPlan RT Image (reference device). Targeting accuracies of both devices to a gold standard fusion were compared to each other (Euclidean Distances between predefined landmarks). The test was repeated 3 times.	Targeting accuracy, Image Fusion Angio: 0.3 mm +/- 0.1 mm Targeting accuracy, iPlan RT Image: 3.2 mm +/- 0.3 mm
Retrospective Study	We used 35 datasets from 16 different clinical sites (11 different scanner types). We performed 2D/3D fusions with Image Fusion Angio. The gold standard fusions were defined by medical experts. Targeting accuracies of predefined landmarks (Euclidean distance to gold standard fusion) were calculated. All fusions were further reviewed by medical experts.	Targeting accuracy: 0.36 mm +/- 0.17 mm The result is similar to the result of the phantom bench test and similar to the findings in the literature.