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

September 26, 2017

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

Re: K170816
Trade/Device Name: Image Fusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, JAK
Dated: September 15, 2017
Received: September 21, 2017

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 (DICE) 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 (DICE) 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,

Michael D. O'Hara 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)*

K170816

Device Name
Image Fusion

Indications for Use *(Describe)*

The Image Fusion Element can be used in clinical workflows that benefit from the co-registration of image data. For example, this applies to navigation systems or medical data information terminals for image processing or image guided surgery in general as well as for treatment planning software for radiosurgery and radiotherapy. The device itself does not have specific clinical indications.

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

Manufacturer:	Brainlab AG Olof-Palme-Str. 9 81829 München Germany Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 5033
Submitter:	Rainer Birkenbach
Contact person:	Alexander Schwiersch
Summary date:	9/15/2017
Device:	Image Fusion
Trade name:	Elements Image Fusion Elements Cranial Distortion Correction Elements Spine Curvature Correction Elements Contrast Clearance Analysis
Common/Classification Name:	System, Image Processing, Radiological
Main Predicate Device:	Mirada XD (K101228)
Secondary Predicate Device:	iPlan (K113732)
Device classification name:	Picture archiving and communications system
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
Intended use:	The Image Fusion Element is an application for the co-registration of image data within medical procedures by using rigid and deformable registration methods. It is intended to align anatomical structures between data sets.
Indications for use:	The Image Fusion Element can be used in clinical workflows that benefit from the co-registration of image data. For example, this applies to navigation systems or medical data information terminals for image processing or image guided surgery in general as well as for treatment planning software for radiosurgery and radiotherapy. The device itself does not have specific clinical indications.

Device description:

The Image Fusion Element is intended to co-register volumetric medical image data (e.g. MR, CT). It allows rigid image registration to adjust different spatial position and orientation of two data sets. It also offers deformable registration to compensate image distortion or spatial deviation between image acquisitions.

The Image Fusion Element gives the possibility to show basic planning content (e.g. objects, points, trajectories) defined from one dataset on another dataset and to display datasets of corresponding anatomic planes simultaneously. Further it could process co-registered data to highlight differences between distinct scanning sequences or to assess the response to a treatment.

Operator Profile
The application is intended to be used by medical professionals and their assistants working in the field of neurosurgery, traumatology or radiotherapy planning.

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

Conditions of use
The Image Fusion Element is designed to be used

- in a hospital office environment or at any other location offering a computer
- in an operating room / suite or in rooms appropriate for surgical interventions

Substantial equivalence:

Image Fusion is part of a new software generation at Brainlab. It contains features for rigid fusion (co-registration) of medical image data, verification of such calculation results as well as a user interface which is substantially equivalent to the reference predicate device iPlan 3.0 (K113732). Further it contains features for deformable registration (elastic fusion) of cranial or spinal image data as well as tools for assessing results of a treatment, which are substantially equivalent to the primary predicate device Mirada XD (K101228).

Conclusion:

Functionality and features considered as substantially equivalent have been verified and validated. The system Image Fusion with its set of functionalities is substantially equivalent to its predicate devices.

Changes to Predicate Device:

The new Image Fusion 3.0 Element enlarges the portfolio of already cleared Brainlab Elements. Central changes compared to the main predicate device iPlan 3.0 are based in focusing on image fusion functionality in general (co-registration and deformable registration).

Technological Characteristics:

	Cleared device feature/specifications Mirada XD (K101228)	Modified device feature/specifications Image Fusion 3.0
Characteristics		
Starting of a deformation calculation	Yes	Yes
Verification of deformation (correction) result	Yes	Yes

	Cleared device feature/specifications iPlan 3.0.6 (K113732): - Cranial - ENT - CMF - Stereotaxy - Spine - Flow - View	Modified device feature/specifications Image Fusion 3.0: - Image Fusion - Cranial Distortion Correction - Spine Curvature Correction - Contrast Clearance Analysis
Characteristics		
Selection of intended application container	Yes	Yes
Import/export of medical data	Yes	Yes
Display of data, Switching of view orientation	Yes	Yes
Starting of a rigid fusion calculation	Yes	Yes
Verification of rigid fusion result	Yes	Yes

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 has been performed in accordance with the Validation 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).