Brainlab AG
% Chiara Cunico
Manager Regulatory Affairs
Olof-Palme-Str. 9
Munich, Bayern 80809
GERMANY

December 16, 2021

Re: K212420
Trade/Device Name: Brainlab Elements, Brainlab Elements Contouring, Brainlab Elements Fibertracking, Brainlab Elements Image Fusion, Brainlab Elements Image Fusion Angio
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ, JAK
Dated: November 10, 2021
Received: November 15, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212420

Device Name
Brainlab Elements, Brainlab Elements Contouring (4.0), Brainlab Elements Fibertracking (2.0), Brainlab Elements Image Fusion (4.0), Brainlab Elements Image Fusion Angio (1.0)

Indications for Use *(Describe)*
Brainlab Elements Contouring provides an interface with tools and views to outline, refine, combine and manipulate structures in patient image data. The generated 3D structures are not intended to create physical replicas used for diagnostic purposes. The device itself does not have clinical indications.

Brainlab Elements Fibertracking is an application for the processing and visualization of cranial white matter tracts based on Diffusion Tensor Imaging (DTI) data for use in treatment planning procedures. The device itself does not have clinical indications.

Brainlab Elements Image Fusion 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. The device itself does not have clinical indications.

Brainlab Elements Image Fusion Angio is a software application that is intended to be used for the co-registration of cerebrovascular image data. The device itself does not have 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

K212420

November 10, 2021

General Information	
Manufacturer	Brainlab AG; Olof-Palme-Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Trade Name	Brainlab Elements, Brainlab Elements Contouring, Brainlab Elements Fibertracking, Brainlab Elements Image Fusion, Brainlab Elements Image Fusion Angio
Classification Name	System, image processing, radiological
Product Code	LLZ, JAK
Regulation Number	892.2050
Regulatory Class	Class II
Panel	Radiology
Predicate Device(s)	Mimics Medical (K183105) – Primary Predicate iPlan (K113732) – Second predicate Image Fusion (K170816) – Third predicate
Reference Device	Brainlab Elements Image Fusion Angio (K190042)

Contact Information	
Primary Contact	**Alternate Contact**
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1. Indication for Use

Brainlab Elements Contouring provides an interface with tools and views to outline, refine, combine and manipulate structures in patient image data. The generated 3D structures are not intended to create physical replicas used for diagnostic purposes. The device itself does not have clinical indications.

Brainlab Elements Fibertracking is an application for the processing and visualization of cranial white matter tracts based on Diffusion Tensor Imaging (DTI) data for use in treatment planning procedures. The device itself does not have clinical indications.

Brainlab Elements Image Fusion 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. The device itself does not have clinical indications.

Brainlab Elements Image Fusion Angio is a software application that is intended to be used for the co-registration of cerebrovascular image data. The device itself does not have clinical indications.

2. Device Description

Brainlab Elements is a medical device for processing of medical images, that is used to support treatment planning of surgical or radio-therapeutical procedures.

The Brainlab Elements applications transfer DICOM data to and from picture archiving and communication systems (PACS) and other storage media devices. They include modules for 2D & 3D image viewing, image processing, image co-registration, image segmentation and 3D visualization of medical image data for treatment planning procedures.

Brainlab Elements main software functionalities include:

- Visualization of medical image data in DICOM format
- Co-registration of different imaging modalities by using both rigid and deformable registration methods
- Processing of co-registered data to highlight differences between distinct scanning sequences or to assess the response to a treatment
- Contouring and delineation of objects and anatomical structures
- Automatic segmentation of anatomical structures
- Manipulation of objects and segmented structures (e.g. splitting, cutting, mirroring, etc.)
- Measuring tools
- Co-registration of cerebrovascular image data
- Visualization of Diffusion Tensor Imaging (DTI) based data and processing of such data to visualize e.g. cranial white matter tracts

The intended users are medical professionals. Typical users as defined in the use case descriptions are:

- Image Guided Surgery: Neurosurgeons, Ear-Nose-Throat (ENT) surgeons and Cranio-Maxillofacial (CMF) surgeons including their assistants
- Radiotherapy: medical professionals who perform radiation treatment planning (medical physicists, radiation oncologists, dosimetrists, physicians, etc.)

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

3. Substantial Equivalence

Item	Information	510 (k)	Product Code; Subsequent Product Code(s)	Subject Device
Primary Predicate device	Mimics Medical	K183105	LLZ	Brainlab Elements Contouring 4.0

Item	Information	510 (k)	Product Code; Subsequent Product Code(s)	Subject Device
Second Predicate device	iPlan (iPlan Cranial, iPlan Stereotaxy, iPlan ENT, iPlan CMF, iPlan View, iPlan Spine)	K113732	JAK; LLZ	Brainlab Elements Fibertracking 2.0; Brainlab Elements Countouring 4.0
Third Predicate device	Image Fusion 3.0	K170816	LLZ; JAK	Brainlab Elements Image Fusion 4.0
Reference Device	Image Fusion Angio 1.0	K190042	LLZ; JAK	Brainlab Elements Image Fusion Angio 1.0.1

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

At a high level, the subject and predicate devices are based on the following same technological elements:

Image Fusion and Image Fusion Angio:
- Principle of image co-registration (rigid and deformable)
- Verification tools
- Viewing of images and DICOM data

Contouring:
- Object segmentation using manual, semi-automatic or fully automatic algorithms
- 3D model calculation
- Measuring functionalities
- Verification tools
- Viewing of images and DICOM data

Fibertracking:
- Automatic DTI data processing
- Region-of-interest (ROI) definition
- 3D visualization

In addition, the subject device indications for use are equivalent to that of the predicate device.

The following technological differences exist between the subject and predicate device(s):

- New/modified user interface
- Fibertracking algorithm improvements (compared to predicate device iPlan)
- Contouring: support of 2D-DSA images (compared to predicate device iPlan)
- Functionality: The device shares the main functionalities of the predicate devices, but is organized in a different way and tools and views are slightly different.

Validation of differences compared to predicate devices:

- The new/modified user interface and views as well as the modified interactions with tools were subject of several formative and summative usability tests.
- Validation tests using retrospective patient data and phantom data were performed to compare the results of the modified algorithm to the results of the algorithm which was present in the predicate device.

4. Performance Data

Product specifications and the implementation of risk control measures have been tested in verification tests for the device according to IEC 62304 and ISO 14971.

Validation tests were performed to demonstrate that the products fulfill critical state of the art requirements:

- Accuracy of co-registrations, generated by the devices Elements Image Fusion and Elements Image Fusion Angio
- Accuracy of automatically segmented objects, generated by the device Elements Contouring
- Accuracy of fiber tracts, generated by the device Elements Fibertracking

In all cases, acceptance criteria for the validation tests were derived from scientific literature.

Usability tests were performed to demonstrate the devices meet usability requirements as defined in IEC 62366.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a major level of concern, since:

- Prior to mitigation of hazards, a failure of the Software could result in death or serious injury of the patient, because the software provides information that directly drives a decision regarding treatment or therapy
- A malfunction of, or a latent design flaw in, the software could lead to an erroneous diagnosis or delay in delivery of appropriate medical care that would likely lead to Minor Injury.

5. Conclusion

The comparison of Brainlab Elements with the predicate devices shows that the Brainlab Elements have similar functionality, intended use, technological characteristics and users like the predicate device(s). Verification and validation activities ensured that the design specifications are met and that Brainlab Elements does not introduce new issues concerning safety and effectiveness. Hence, Brainlab Elements is substantially equivalent to the predicate device(s).