April 19, 2023

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

Re: K223552
Trade/Device Name: Brainlab Elements - Trajectory Planning (2.6), Elements Stereotaxy, Elements Lead Localization, Elements Trajectory Planning Cranial
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: November 25, 2022
Received: November 25, 2022

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 (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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2023.04.19 18:01:44 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
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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)*
K223552

Device Name
Brainlab Elements Trajectory Planning (2.6), Elements Stereotaxy, Elements Lead Localization, Elements Trajectory Planning Cranial

Indications for Use *(Describe)*

Brainlab Elements Trajectory Planning software is intended for pre-, intra- and postoperative image-based planning and review of either open or minimally invasive neurosurgical and neurological procedures. Its use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate for the placement of instruments/devices and where the position of the instrument/device can be identified relative to images of the anatomy.

This includes, but is not limited to, the following cranial procedures (including frame-based stereotaxy and frame alternative-based stereotaxy):
• Catheter placement
• Depth electrode placement (SEEG procedures)
• Lead placement and detection (DBS procedures)
• Probe placement
• Cranial biopsies

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

General Information	
Manufacturer	Brainlab AG; Olof-Palme Str.9; 81829, Munich, Germany
Establishment Registration	8043933
Trade Names	• Brainlab Elements – Trajectory Planning (2.6) • Elements Stereotaxy • Elements Lead Localization • Elements Trajectory Planning Cranial
Classification Name	Neurological Stereotaxic Instrument
Product Code	HAW
Regulation Number	882.4560
Regulatory Class	II
Panel	Neurology
Primary Predicate Device	(K211544) Brainlab Elements Trajectory Planning (2.5)
Additional Predicate Device	(K092192) Waypoint Stereotactic System
Contact Information	
Primary Contact	Sadwini Suresh QM Consultant Regulatory Affairs Phone: +49 89 99 15 68 0 Email: regulatory.affairs@brainlab.com
Alternate Contact	Chiara Cunico Senior Manager Regulatory Affairs Phone: +49 89 99 15 68 0 Email: chiara.cunico@brainlab.com

1. Indications for Use

Brainlab Elements - Trajectory Planning software is intended for pre-, intra- and postoperative image-based planning and review of either open or minimally invasive neurosurgical and neurological procedures.
Its use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate for the placement of instruments/devices and where the position of the instrument/ device can be identified relative to images of the anatomy.
This includes, but is not limited to, the following cranial procedures (including frame-based stereotaxy and frame alternative-based stereotaxy):

- Catheter placement
- Depth electrode placement (SEEG procedures)
- Lead placement and detection (DBS procedures)
- Probe placement
- Cranial biopsies

2. Device Description

Brainlab Elements Trajectory Planning is a software used to plan minimally invasive possible pathways ('Trajectories') for surgical instruments on scanned images. It is used for the processing and viewing of anatomical images (for example: axial, coronal and sagittal reconstructions, etc.) and corresponding planning contents (for example: co-registrations, segmentations, fiber tracts created by compatible applications and stored as DICOM data) and the planning of trajectories based on this data. The device is also used for the creation of coordinates and measurements that can be used as input data for surgical intervention (e.g.: stereotactic arc settings or FHC STarFix platform settings). Depending on the workflow and available licenses, Brainlab Elements Trajectory Planning might be used in different roles where only specific application features are available.

The following roles are available for Trajectory Planning:

• Trajectory (Element): allows the creation of trajectories
• Stereotaxy (Element): allows the creation of trajectories and supports stereotactic procedures based on Stereotactic Arc Settings or FHC STarFix platform settings
• Lead Localization (Element): allows the creation of trajectories and automatic detection of leads in post-operative images.

All roles are enabled to be used for cranial trajectory planning procedures after installation of Trajectory as well as the corresponding workflow files for Cranial Planning, Stereotactic Planning or Post-Op Review.

3. Substantial Equivalence

The Subject Device has similar intended use and technological features as the predicate devices. An overview of the similarities and differences can be found in the tables below:

Device	Name
Primary Predicate Device	(K211544) Brainlab Elements Trajectory Planning (2.5)
Additional Predicate device	(K092192) Waypoint Stereotactic System

Topic/ Feature	Primary Predicate: (K211544) Brainlab Elements Trajectory Planning (2.5)	Subject Device (Trajectory Planning 2.6)	Comment
Indications for use	The Brainlab Elements Trajectory Planning software is intended for pre-, intra- and postoperative image-based planning and review of either open or minimally invasive neurosurgical and neurological procedures. Its use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate for the placement of instruments/devices and where the position of the instrument/ device can be identified relative to images of the anatomy. This includes, but is not limited to, the following Cranial procedures (including frame-based stereotaxy and frame alternative-based stereotaxy): - Catheter placement - Depth electrode placement (SEEG procedures) - Lead placement and detection (DBS procedures) - Probe placement - Cranial biopsies	The Brainlab Elements Trajectory Planning software is intended for pre-, intra- and postoperative image-based planning and review of either open or minimally invasive neurosurgical and neurological procedures. Its use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate for the placement of instruments/devices and where the position of the instrument/ device can be identified relative to images of the anatomy. This includes, but is not limited to, the following Cranial procedures (including frame-based stereotaxy and frame alternative-based stereotaxy): - Catheter placement - Depth electrode placement (SEEG procedures) - Lead placement and detection (DBS procedures) - Probe placement - Cranial biopsies	No Changes compared to the primary predicate.
User Profile	The target user group are healthcare professionals educated for the planning and	The target user group are healthcare professionals educated for the planning and	No Changes compared to the primary predicate.

Topic/ Feature	Primary Predicate: (K211544) Brainlab Elements Trajectory Planning (2.5)	Subject Device (Trajectory Planning 2.6)	Comment
	execution of functional neurosurgery procedures. These include neurosurgeons and neurologists.	execution of functional neurosurgery procedures. These include neurosurgeons and neurologists.	
Hardware requirements	Trajectory Planning can be used on computer platforms that fulfill the defined minimum requirements: - Operating System: Windows 7 64bit SP1 - Minimum 4 logical cores - Minimum RAM: 6 GB - Graphics: Direct X compatible - Display Resolution: 1920 x 1080 (Full HD)	Trajectory Planning can be used on computer platforms that fulfill the defined minimum requirements: - Operating System: Windows 7 64bit SP1 - Minimum 4 logical cores - Minimum RAM: 6 GB - Graphics: Direct X compatible - Display Resolution: 1920 x 1080 (Full HD)	No Changes compared to the primary predicate.
View and Adjust	N/A	Adjust Windowing via dedicated windowing parameter controls and presets	New GUI functionality added to the Subject Device. Only additional GUI options are offered for adjusting the windowing
Measurements	Make Measurements in the selected dataset with different measurement tools: - Margin Measurement: Create a margin around a trajectory - Distance Measurement: Measure the distance between two points	Make Measurements in the selected dataset with different measurement tools: - Point Measurement: Mark individual points in the dataset and get additional information such as the DICOM coordinates of the point, the grey values of the image dataset at this point or the AC/PC coordinates of the point - Angle Measurement: Measure the angle between two lines	Only additional tool options for measuring points, distances or angles are offered .

Topic/ Feature	Primary Predicate: (K211544) Brainlab Elements Trajectory Planning (2.5)	Subject Device (Trajectory Planning 2.6)	Comment
		- Multiline Measurement: Measure the distance between several points	
Supported Non-Brainlab Stereotactic Hardware	N/A	Inomed SUSy Arc interfacing with Inomed Titanium or Inomed Open Ceramic Headring	Additional stereotactic arc system supported with the subject device.
Stereotactic Platform Support	N/A	FHC STARFIX Stereotactic Platform is supported	Added support of FHC STarFix Stereotactic Platforms

Topic/ Feature	Additional Predicate: (K092192) Waypoint Stereotactic System	Subject Device (Trajectory Planning 2.6)	Comment
Indications for use	The WayPoint Stereotaxic System is intended to be used with commercially available stereotactic systems for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, implantable electrodes or other instruments in the brain or nervous system.	The Brainlab Elements Trajectory Planning software is intended for pre-, intra- and postoperative image-based planning and review of either open or minimally invasive neurosurgical and neurological procedures. Its use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate for the placement of instruments/devices and where the position of the instrument/ device can be identified relative to images of the anatomy. This includes, but is not limited to, the following Cranial procedures (including frame-based stereotaxy and frame alternative-based stereotaxy): - Catheter placement - Depth electrode placement (SEEG procedures) - Lead placement and detection (DBS procedures) - Probe placement	Similar indications for use.

Topic/ Feature	Additional Predicate: (K092192) Waypoint Stereotactic System	Subject Device (Trajectory Planning 2.6)	Comment
		- Cranial biopsies	
	The application allows the user to configure and review trajectory planning results to be realized using FHC STarFix Platforms. These are patient/case specific frameless stereotactic platforms manufactured and delivered by FHC Inc.	The application allows the user to configure and review trajectory planning results to be realized using FHC STarFix Platforms. These are patient/case specific frameless stereotactic platforms manufactured and delivered by FHC Inc.	No changes.
Anchor Detection	User can detect (FHC WayPoint) anchors on CT scans that are used as interface to the patients head (based on stereotactic registration).	User can detect (FHC WayPoint) anchors on CT scans that are used as interface to the patients head (based on stereotactic registration).	No changes.
Stereotactic Platforms	The following FHC STarFix Stereotactic Platforms can be used (as selected by the user): - Four legged Unilateral Platforms (2h2h) - Four legged Bilateral Platforms (2h2h, 2b2b) - Three Legged Unilateral Platforms (Unilateral) - Staged Bilateral Platforms (Epilepsy Multi-Hub)	The following FHC STarFix Stereotactic Platforms can be used (as selected by the user): - Four legged Unilateral Platforms (2h2h) - Four legged Bilateral Platforms (2h2h, 2b2b) - n/a - n/a	Minor Difference - Only four legged stereotactic positioning platforms are supported (reducing the number of options) - Provided options are similar to the predicate.
Registration	The following registration constraints are applied:	The following registration constraints are applied:	- Supporting only 4 anchors furthermore prevents wrong mounting of the platform

Topic/ Feature	Additional Predicate: (K092192) Waypoint Stereotactic System	Subject Device (Trajectory Planning 2.6)	Comment
	- One and the same anchor length (4 mm or 5 mm) is supported for the required set of anchors - 3 or 4 anchors are supported - Anchor detections have to be accepted by the user	- One and the same anchor length (4 mm or 5 mm) is supported for the required set of anchors - Only 4 anchors are supported - Anchor detections have to be accepted by the user	- Overall functionality is similar to the predicate.

4. Performance Data

Verification

Software Verification:
Software verification was performed, verifying the software requirements through integration tests, and unit tests. Incremental test strategies have been set up after verification of the first release candidate for changes with limited scope. In this case, an impact analysis of the modifications is performed and tests to be performed are identified and planned correspondingly. That means, not all tests have to be performed but only a subset, as some of the previous tests are not affected by the change and remain therefore valid.
Software verification verifies all specifications, including SOUP items and cybersecurity.

Bench Testing

In addition to the routine verification tests, the following performance tests were carried out for the Subject Device.

FHC anchor detection:

The objective of these validative tests is to verify for Trajectory Planning 2.6, that accuracy and robustness of the automatic and semi-automatic WayPoint anchor detection on CT data for FHC's 4 mm and 5 mm bone anchors are non-inferior to the SW application WayPoint™ Planner Software. The acceptance criteria specified in the test plan regarding the Brainlab automatic and semi-automatic anchor detection algorithm were fullfilled.

Summative Usability Evaluation:

Within version 2.6 of Trajectory Planning (Subject Device) the support of STarFix plaforms for DBS procedures including detection of WayPoint bone anchors and platform planning was introduced and thus the whole workflow of planning a STarFix platform in Stereotaxy Element was subject to summative evaluation. In addition, locking of plans and overlay/blending of two fused images sets were added as features as well and were included in the summative evaluation.
Additionally, the new interaction with the coordinates (e.g.AC/PC) caused by GUI changes was also evaluated.

5. Conclusion

The performed verification and validation activities established that the set requirements were met and that the device performs as intended.
The Subject Devices' comparison with the Predicate Devices establishes that they have similar functionality, intended use and technological characteristics. Therefore, we consider that the Subject Device can be considered substantially equivalent to the predicate device.