November 3, 2021

Brainlab AG
Chiara Cunico
Manager Regulatory Affairs
Olof-Palme-Str. 9
Munich, Germany 81829

Re: K211544
Trade/Device Name: Trajectory Planning, Elements Trajectory Planning, Elements Lead Localization
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: September 29, 2021
Received: October 4, 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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
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)*
K211544

Device Name
Trajectory Planning, Elements Trajectory Planning, Elements Lead Localization

Indications for Use *(Describe)*
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

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

November 3, 2021

General Information	
Manufacturer	Brainlab AG; Olof-Palme-Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Trade Name	Trajectory Planning, Elements Trajectory Planning, Elements Lead Localization
Classification Name	Neurological Stereotaxic Instrument
Product Code	HAW
Regulation Number	882.4560
Regulatory Class	Class II
Panel	Neurology
Predicate Device(s)	iPlan K101627

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

2. Device Description

Trajectory planning is a software device which 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, trajectories, etc.). 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).

The software is used in three different configurations:

1. Trajectory (Element): allows the creation of trajectories
2. Stereotaxy (Element): allows the creation of trajectories and supports also frame based procedures
3. Lead Localization (Element): allows the creation of trajectories and automatic detection of leads in post-operative images

The software takes (DICOM) data as input and provides (DICOM) data as outputs. This data can be transferred by removable memory devices like USB sticks or via network.

The user interaction can be done with a touchscreen and/or with a mouse, optionally combined with a keyboard on a laptop which fulfill minimum requirements.

3. Substantial Equivalence

The Subject Device is similar to the predicate device in terms of:

- Support of frame based procedures including stereotactic localization and arc settings calculation
- Trajectory planning on multi-modal co-registration images
- Multiple views for reconstructed medical images
- Visualization for supplemental information like segmented structure and fiber tracts
- Definition and usage of AC/PC coordinate system for Trajectory Planning

The Subject Device differs from the predicate device in terms of:

- Additional indications included for SEEG procedures, DBS procedures, Probe placement
- Spine and ENT indications
- Additional stereotactic hardware support (Elekta Vantage)
- Predicate device was split into multiple medical software modules
- Addition of automatic lead detection in CT images
- User Interfaces

4. Performance Data

Software Verification

Software verification 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."

Software verification was carried out for all the specifications and all tests met the acceptance criteria. In addition to the verification activities, the risk analysis shows that all relevant hazards have been taken into consideration, that risk control is complete and that the corresponding measures are in place.

Usability

Data from the Summative Usability test concluded that there is no indication that the use of the device could lead to critical errors resulting in a hazardous situation for patient or user.

Clinical Evaluation

Clinical claims were supported via data from literature and post market data collected.

5. Conclusion

The comparison of the Subject Device with the predicate device shows that the device has similar functionality, intended use, technological characteristics, and typical users as the predicate device. Verification and validation activities ensured that the design specifications are met and that the Subject Device substantially equivalent to the predicate device.