January 28, 2025

Brainlab AG
Esther Moreno Garcia
Manager Regulatory Affairs
Olof-Palme Str.9
Munich, 81829
Germany

Re: K243698
Trade/Device Name: Alignment System Cranial, with Alignment Software Cranial with LITT; Cirq Alignment Software Cranial Biopsy; Cirq Alignment Software Cranial sEEG; VarioGuide Alignment Software Cranial; Cirq Alignment Software Cranial LITT
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: November 29, 2024
Received: November 29, 2024

Dear Esther Moreno Garcia:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2025.01.28 17:39:20 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243698

Device Name
Alignment System Cranial, with Alignment Software Cranial with LITT;
Cirq Alignment Software Cranial Biopsy;
Cirq Alignment Software Cranial sEEG;

Indications for Use *(Describe)*
Alignment System Cranial is intended to plan and to achieve a trajectory with surgical instruments during cranial stereotactic procedures.

The indications for use are biopsy of intracranial lesions, placement of stereoelectroencephalography (SEEG) electrodes and placement of anchor bolts for laser interstitial thermal therapy (LITT).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

January 28th, 2025

General Information	
Manufacturer	Brainlab AG; Olof-Palme-Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Trade Name	Alignment System Cranial, with Alignment Software Cranial with LITT Cirq Alignment Software Cranial Biopsy Cirq Alignment Software Cranial sEEG VarioGuide Alignment Software Cranial Cirq Alignment Software Cranial LITT
Classification Name	Neurological Stereotaxic Instrument
Product Code	HAW
Regulation Number	882.4560
Regulatory Class	Class II
Panel	Neurology
Predicate Device(s)	Primary Predicate: K191597 Stealth Autoguide System Secondary Predicate: K223864 Alignment System Cranial

Contact Information	
Primary Contact	**Alternate Contact**
Esther Moreno Garcia Manager Regulatory Affairs Phone: +49 89 99 15 68 0 Email: regulatory.affairs@brainlab.com	Chiara Cunico Senior Manager Regulatory Affairs Phone: +49 89 99 15 68 0 Email: chiara.cunico@brainlab.com

1. **Indication for Use**

   Alignment System Cranial is intended to plan and to achieve a trajectory with surgical instruments during cranial stereotactic procedures.

   The indications for use are biopsy of intracranial lesions, placement of stereoelectroencephalography (SEEG) electrodes and placement of anchor bolts for laser interstitial thermal therapy (LITT).

2. **Device Description**

   The subject device Alignment System Cranial is an image guided surgery system intended to support the surgeon to plan and to achieve a trajectory with surgical instruments during cranial stereotactic procedures using optical tracking technology.

For this purpose, the Alignment System Cranial consists of a combination of hardware and software. The Alignment Software Cranial with LITT 2.1 is installed on an Image Guided Surgery (IGS) platform (Curve, Curve Navigation 17700, Kick 2 Navigation Station or Buzz Navigation) consisting of a computer unit, a touch display and an infrared tracking camera. During surgery, the software tracks the position of instruments in relation to the patient anatomy and identifies this position on pre- or intraoperative images. The position of the surgical instruments is continuously updated on these images by optical tracking. This position information is used by the software to align either passive or active positioning devices to a planned trajectory for subsequent surgical steps.

The Alignment System Cranial has different configurations of hardware devices depending on which positioning device is used and which indication is performed. The Alignment Software Cranial with LITT 2.1 supports the active positioning devices Surgical Base System 1.4 and Cirq Arm System 2.0 (+ Cirq Robotic Alignment Module + Cirq Robotic Disposable Kinematic Unit) as well as the passive positioning device VarioGuide. Both types of positioning devices consist of articulated arms with different joints where additional devices and surgical instruments can be attached to for further manual or robotic alignment to a defined trajectory.

In addition, the subject device offers a set of indication specific instruments to support biopsy, sEEG and LITT procedures. This instrumentation consists of instrument holders, tracking arrays, guide tubes, reduction tube, bone anchors, drill bits and depth stops. None of the instruments is delivered sterile. All patient contacting materials consist of different alloys of stainless steel.

The Alignment Software Cranial with LITT has the following accessories:

- Automatic Registration providing an automatic registration for subsequent use.
- Automatic Registration iMRI providing an automatic image registration for intraoperatively acquired MR images.

3. Substantial Equivalence

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Characteristic	Primary Predicate K191597	Secondary Predicate K223864	Subject device
Indications for use	The Stealth Autoguide System is a positioning and guidance system intended for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons to guide standard neurosurgical instruments, based on a pre-operative plan and feedback from an image-guided navigation system with three-dimensional imaging software. The Stealth Autoguide System is a remotely-operated positioning and guidance system, indicated for any neurological condition in which the use of stereotactic surgery may be appropriate (for example, stereotactic biopsy, stereotactic EEG, laser tissue ablation, etc.).	Alignment System Cranial is intended to support the surgeon to plan and to achieve a trajectory with surgical instruments during cranial stereotactic procedures. The indications for use are biopsy of intracranial lesions and placement of stereoelectroencephalography (SEEG) electrodes.	Alignment System Cranial is intended to plan and to achieve a trajectory with surgical instruments during cranial stereotactic procedures. The indications for use are biopsy of intracranial lesions, placement of stereoelectroencephalography (SEEG) electrodes and placement of anchor bolts for laser interstitial thermal therapy (LITT). New indication LITT is equivalent to primary predicate, biopsy and sEEG are equivalent to both predicates.
Localization technique	Optical markers on tool holder	Infrared tracking camera is recognizing infrared passive markers Instrument tracking in relation to the patients anatomy.	Same as both predicates

System accuracy	Under representative worst case configuration: Mean navigation accuracy of ±2 mm and angular axis displacement of ±2°	Under representative worst case configuration: Mean navigation accuracy of ±2 mm and angular axis displacement of ±2°	Same as both predicates
Operating principle	Preoperative images (StealthStation) Surgical planning (StealthStation) Patient registration Guidance of instruments Trajectory alignment	Preoperative images Surgical planning Patient registration Guidance of instruments Trajectory alignment with Cirq Arm System plus Cirq Robotic Alignment Module or with the Varioguide	Same as secondary predicate and similar to primary predicate.
Planning software	Compatible with: S8 Cranial v1.1 Synergy Cranial v.3.1	Compatible with: Cranial 3.1 Trajectory Planning 2.5 and 2.6	Similar to secondary predicate. The Cranial 3.1 software is no longer needed as the Subject Device includes a new component Cranial Instrument Setup 3.0, providing the features for instrument handling.
Alignment Instrumentation	Navigated Trajectory Guide Tool Holders (Drill Guides, Reducing Tubes) Height Guides Tapping Tube	Alignment Guide Tubes Instrument Holders, Tracking Arrays Cranial Drill Bits + Depth Stops Bone Anchors (for biopsy and sEEG)	Similar to both preidcates Alignment instrumentation is generally used in all devices with a combination of holders, guides and tubes. Compared to secondary predicate, instrumentation has been extended to support new LITT indication.
Instrument fixation	Special tool holders for different applications mounted to the Stealth AutoGuide	With Cirq Arm System: Cirq Robotic Disposable Kinematic Unit to which the instrument holder is attached.	Mechanical connection is used in all devices for instrument fixation. Identical to secondary predicate.

		With Varioguide: Different Disc sets are mechanically connected depending on guiding diameter.	
Alignment process	Fine alignment robotically performed by Autoguide	With Cirq Arm System: -Rough alignment: Manual positioning of Cirq Arm System with Autopilot feature (Alignment Software) close to final position -Fine alignment: Robotic movement of Cirq Robotic Alignment Module With Varioguide: Rough and fine alignment by manual positioning of VarioGuide along planned trajectory with Autopilot feature (Cranial Navigation)	Similar alignment process as Predicate 1 and identical to Predicates 2.
Patient Registration	Optical Registration Device (via StealthStation)	Optical registration done with Registration 3.6. Methods: Surface matching and landmark registration Surface matching: Landmarks (used for pre-registration) are delivered by an AI/ML based model.	Same registration methods as in secondary predicate. There have been no changes to the AI/ML algorithm.
IGS Platforms	StealthStation surgical navigation platform consisting of computer, touch monitor and stereotactic camera.	Curve, Curve Navigation, Kick and Buzz Navigation models are used, consisting of computer, touch monitor and IR camera.	Similar to predicates. A new platform model (Curve Navigation 17700 #17701) was released but with overall same components and operating principle.

4. Performance Data

The following testing was conducted on the Subject Device to establish substantial equivalence with the predicate devices:

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 Device Software Functions". These include successful implementation of product specifications, incremental testing for different release candidates, testing of risk control measures, compatibility testing or cybersecurity tests. The documentation level for this software is enhanced.

Usability Evaluation

Formative usability was carried out according to the standard IEC 62366-1 "Medical devices – Part 1: Application of usability engineering to medical devices" in a simulated clinical environment to validate the LITT workflow with the Cirq Arm System positioning device. This covered aspects such as the guidance provided by the software, the assembly of the arm, handling of different instruments, etc. with focus on the main differences implemented for LITT. The results confirmed that the LITT workflow is comparable in terms of user interaction to the biopsy and SEEG workflows, already present in the secondary predicate.

System accuracy testing

The positional and angular navigation accuracy for placement of anchor bolts in LITT procedures of the Subject Device including the software, the platforms and the instruments was evaluated considering a realistic clinical setup and representative worst case scenarios.

N of registrations	Total N of samples	Error Type	**Mean Error**	SD	95th perc.	99th perc	99% upper CI
6	37	Positional [mm]	**1.19**	0.50	1.83	1.90	1.40
		Angular [°]	**0.86**	0.39	1.52	1.57	1.03

The above results show the following acceptance criteria are fulfilled:

- Mean Positional Error of the placed instrument's tip ≤ 2 mm
- Mean Angular Error of the placed instrument's axis ≤ 2°

Therefore, the Subject Device achieves the same accuracy performance as both predicate devices.

Electrical safety and electromagnetic compatibility (EMC)

Compliance to electrical safety, RFID and EMC was evaluated on the Subject device according to the standards: IEC 60601-1, AIM 7351731 and IEC 60601-1-2. The tests have shown that the subject device performs as intended.

Instruments

- Biocompatibility assessment acc. ISO 10993-1 considered the materials used in the devices, manufacturing process, processing, biological and chemical test data, and the history of safety and effectiveness of the device materials in contact with the human body.
- Cleaning, disinfection and sterilization evaluation was carried out for instruments and sterilization trays considering the FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”.
- Mechanical properties of instruments were assessed by performing life cycle simulations and verification of clearance fits, material fatigue, functionality, etc.

No clinical testing was needed for the Subject Device since optical tracking technology in the scope of image guided surgery for the included indications for use is well established in the market.

5. Conclusion

The comparison of the Subject Device with the predicate devices shows that the Alignment System Cranial, with Alignment Software Cranial with LITT has similar functionality, intended use and technological characteristics as the predicate devices. Based on the comparison to the predicates and the performance testing conducted, the Subject Device is considered substantially equivalent to the predicate devices.