June 23, 2025

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

Re: K243142
Trade/Device Name: Cranial 4Pi Immobilization
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: May 2, 2025
Received: May 23, 2025

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 (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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of 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)*
K243142

Device Name
Cranial 4Pi Immobilization

Indications for Use *(Describe)*
Cranial 4Pi is intended for patient immobilization in radiotherapy and radiosurgery procedures.
Cranial 4Pi is indicated for any medical condition in which the use of radiotherapy or radiosurgery may be appropriate for cranial and head & neck treatments.

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

June 23, 2025

General Information	
Manufacturer	Brainlab AG; Olof-Palme Str.9; 81829, Munich, Germany
Establishment Registration	8043933
Trade Name	Cranial 4Pi Immobilization
Classification Name	Medical charged-particle
Product Code	IYE
Regulation Number	892.5050
Regulatory Class	II
Panel	Radiology
Predicate Device	K202050 - Cranial 4Pi Immobilization

Contact Information	
Primary Contact	**Alternate Contact**
Sadwini Suresh QM Consultant 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. Indications for use

Cranial 4Pi is intended for patient immobilization in radiotherapy and radiosurgery procedures.

Cranial 4Pi is indicated for any medical condition in which the use of radiotherapy or radiosurgery may be appropriate for cranial and head & neck treatments.

2. Device Description

Cranial 4Pi is an assembly of the following medical device/ accessory groups:

- CRANIAL 4PI OVERLAYS (CRANIAL 4PI CT OVERLAY, CRANIAL 4PI TREATMENT OVERLAY)
- CRANIAL 4PI HEADRESTS (CRANIAL 4PI HEADREST STANDARD, CRANIAL 4PI HEADREST LOW-NECK, CRANIAL 4PI HEADREST PLATFORM)
- CRANIAL 4PI HEADREST INLAYS (CRANIAL 4PI HEADREST INLAY STANDARD, CRANIAL 4PI HEADREST INLAY OPEN FACE, CRANIAL 4PI HEADREST INLAY H&N, CRANIAL 4PI HEAD SUPPORT STANDARD, CRANIAL 4PI HEAD SUPPORT WIDE)

- CRANIAL 4PI MASKS (CRANIAL 4PI BASIC MASK, CRANIAL 4PI OPEN FACE MASK, CRANIAL 4PI EXTENDED MASK, CRANIAL 4PI STEREOTACTIC MASK, CRANIAL 4PI STEREOTACTIC MASK 3.2MM)
- CRANIAL 4PI WEDGES AND SPACERS (CRANIAL 4PI WEDGE 5 DEG., CRANIAL 4PI WEDGE 10 DEG., CRANIAL 4PI SPACER 20MM, CRANIAL 4PI INDEXING PLATE)

The Cranial 4Pi Overlays are medical devices used for fixation of the patient in a CT- resp. linear accelerator - environment.

The Cranial 4Pi Headrests and the Cranial 4Pi Headrest Inlays are accessories to the Cranial 4Pi Overlays to allow an indication specific positioning of the patient's head and neck. The Cranial 4Pi Wedges and Spacers are accessories to the Cranial 4Pi Headrest Platform to adapt the inclination of the head support to the patients necks.

The Cranial 4Pi Masks are accessories to the Cranial 4Pi Overlays used for producing individual custom-made masks for patient immobilization to the Cranial 4Pi Overlay.

3. Substantial Equivalence

Topic/ Feature	**Predicate Device** **Cranial 4Pi Immobilization**	**Subject Device** **Cranial 4Pi Immobilization**
K-Number	K202050	K243142
Indications for use	The Cranial 4Pi Immobilization is a device used for immobilization of the patient's • cranial area • head and neck area in a CT- and linear accelerator environment. The Cranial 4Pi Immobilization device is indicated for any medical condition in which the use of radiotherapy or radiosurgery may be appropriate for cranial and head & neck treatments.	Cranial 4Pi is intended for patient immobilization in radiotherapy and radiosurgery procedures. The Cranial 4Pi device is indicated for any medical condition in which the use of radiotherapy or radiosurgery may be appropriate for cranial and head & neck treatments.

Topic/ Feature	Predicate Device	Subject Device
Cranial 4Pi Headrest Cranial 4Pi Wedges and Spacers	For the rear head support of the patient two carbon headrests with three foam inlays that are attached to the Overlay Board and that have a head shaped form are available. The inlays support the head in a neutral position or tilt the patients head slightly forward or backwards depending on the treatment indications.   	An additional third headrest (Cranial 4Pi Headrest Platform) will be added to the system to treat patients that cannot lie down flat because of kyphosis or other special body indications. The headrest platform connects to the current interface on the Overlay Board and provides an even platform on the Overlay Board level. The headrest platform has an interface to the Cranial 4Pi Indexing Plate that has an interface to a selection of wedges and a spacer that will be provided with the headrest. In addition a head support will be added on top that connects to the patients head and will be available in two shapes (standard and wide). The wedges will be available in two angulations (5 and 10 degrees) and the spacer with a thickness of 20 mm.  

Topic/ Feature	Predicate Device	Subject Device
Cranial 4Pi Stereotactic Mask	Cranial 4Pi Stereotactic Mask has a three sheet design with a rear mask, a middle mask and a 2 mm thick top mask. 	A new mask variant is created that is almost identical to the Cranial 4Pi Stereotactic Mask but with a 3.2 mm thick top mask for higher stability.

4. Performance Data

Biocompatibility, reprocessing and shelf life

For the subject devices a risk assessment was performed to assess which endpoints are required for biocompatibility testing of the foam material. Cytotoxicity testing was performed and described below. Regarding Irritation and Sensitization the risk is mitigated by the limited exposure of the patient to the material and the contact with intact skin only. As concluded after cytotoxicity testing the amount of non-reacted ducts is considered to be low. Exposure to potentially irritant or sensitizing substances is thus also considered low with regards to the raw material composition and omission of in vivo testing is justified in line with ISO 10993-2.

Regarding chemical information Polyurethanes are widely used for manufacture of medical devices including tubing, gloves or larger devices such as medical beds. Evaluation of safety data sheets of the utilized polyurethane coating has been conducted. No potentially hazardous substances such as CMRs, EDs, nanomaterials or materials of biological origin are part of the composition.

The coating of the foam parts consists of a base polymer mix as well as a hardener (10 %). During crosslinking (hardening) of the coating the reaction educts are expected to react to a high degree given the specific mixture of the components. Thus, the risk of unbound residues is considered low.

Sensitization Testing:

The study was performed according to ISO 10993-10.

Saline Extraction: No sensitization reactions were observed in test animals. The test group animals did not exhibit scores higher than those of the negative control animals.

Cottonseed Oil Extraction: No sensitization reactions were observed in test animals. The test group animals did not exhibit scores higher than those of the negative control animals.

According to the criteria for this test, the test article did not elicit sensitization reactions in the animals used in this study. Under similar treatment conditions, all positive control animals exhibited a strong sensitization response to the challenge dose compared to that of the control. The results from this study demonstrate that the guinea pigs are able to detect sensitizing agent (i.e., DNCB). This validates sensitivity of this test.

Irritation Testing:

This study was conducted according to ISO 10993-23 guidelines. All animals appeared healthy during the course of the study. Based on erythema and edema scores, no irritation was observed on the test sites when compared to the control. The test article extracted in saline and cottonseed oil met the requirements for the Intracutaneous (Intradermal) Reactivity Test using conditions specified in this report.

Under similar treatment conditions, all positive control animals used in the historical positive control study exhibited strong irritation responses to the positive control. The results from the historical positive control study demonstrate that the rabbits are able to detect irritating agents. The skin reactions elicited by the positive control validate the sensitivity of this test.

Mechanical Verification tests:

All mechanical tests relevant for fulfillment of IEC 60601-1 requirements were carried out.

Dosimetry tests:

Tests to verify that dose attenuation is acceptable with the hardware components were carried out successfully.

Compatibility tests:

Compatibility with ExacTrac Dynamic 2.0 was tested successfully.

Mask Stability:

Technical validation test to prove that the Cranial 4Pi SRS mask 3.2 mm that is identical to the Cranial 4Pi SRS mask but having a 3.2 mm top mask sheet instead of 2mm has a higher stability against head movement was carried out successfully.

Usability Evaluation:

For usability evaluation of the subject devices first a comparison was done for the interface of the Cranial 4Pi headrest platform with wedges and spacer and the current Cranial 4Pi system (comprising a rear mask, middle mask and top mask) already on the market. Also an equivalence assessment to a state of the art solution by Orfit has been performed. The main differences that were found were in the attachment mechanism and adjustment of the

longitudinal position as well as the usage of a rear-mask . Then a formative usability evaluation has been performed in three different clinics with seven participants to evaluate the usability of the subject devices.

5. Conclusion

The comparison of the Subject Device with the predicate device shows that the modified Cranial 4Pi Immobilization has similar functionality, intended use and technological characteristics as the predicate device. Based on the comparison to the predicate and the performance testing conducted, the Subject Device is considered substantially equivalent to the predicate device.