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

August 19, 2020

Re: K202050
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: July 21, 2020
Received: July 24, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202050

Device Name
Cranial 4Pi Immobilization

Indications for Use *(Describe)*
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.

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

K202050

July 21, 2020

General Information	
Manufacturer	Brainlab AG
Establishment Registration	8043933
Device Name	Accelerator, Linear, Medical
Trade Name	Cranial 4Pi Immobilization
Classification Name	Medical charged-particle radiation therapy system
Product Code	IYE
Regulation Number	892.5050
Regulatory Class	II
Panel	Radiology
Predicate Device and K Number	Frameless Radiosurgery Components - K053500

Contact Information	
Primary Contact	**Alternate Contact**
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1. Intended 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.

2. Device Description

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 an accessory to medical device ExacTrac Dynamic.

The Cranial 4Pi Immobilization group of devices is used for fixation and repositioning of the patient's head and neck in a CT- and linear accelerator environment.
The SRS 4Pi CT Table Overlay (43430) is a medical device used for fixation and repositioning of the patient's head and neck in a CT- environment.
The mask sets Cranial 4Pi Stereotactic Mask (43450) / Cranial 4Pi Basic Mask (43451) / Cranial 4Pi Openface Mask (43452) are medical devices used for producing custom-made masks for patient fixation to the Overlay Board in a CT- and linear accelerator environment.

The device is portable. The system consists of two Overlays, three types of thermoplastic mask sets with the corresponding rear head support and a Target Pointer. The system fixates a patient mechanically to hold them still during CT scanning and again during Treatment. The Overlays (one for CT, one for Linac room) are used to rigidly attach to multiple Table top/Couch Top types and to provide an interface to the Mask sets. The Target Pointer is used for performance of isocenter quality assurance procedures in a linear accelerator environment.

Key Performance Specifications/Characteristics of the Device:

Primary Operating Function: Immobilization of patient's head or head and neck.

Series of tasks and user interactions that are frequently used and risk related

- **Task: Attachment of Treatment Overlay to treatment couch top**
  - User Interaction: Place Overlay on couch top
  - User Interaction: Fixate Overlay to couch top with indexing brackets and locking latch mechanism

- **Task: Immobilization of patient with mask**
  - User Interaction: Attach rear mask to Overlay
  - User Interaction: Attach top mask to Overlay

Use Scenario

The following scenario describes the frequent use scenario and reflects already the worst case/ hazard related scenario.

An oncologist sends a patient with head or neck tumor for radiosurgery/radiotherapy treatment. The patient will receive certain dose fractions according to a previously defined treatment plan. Therefore the patient lies on a couch with an Overlay during the CT imaging and for the treatment procedure. To immobilize the patient , thermoplastic mask sets (Stereotactic mask or Basic mask or Openface mask) in combination with the rear head support, are individually molded for each patient. A radiographer attaches the Mask set to the Overlay. Depending on the treatment indication the device is used for single-fraction treatments (radiosurgery) as well as for multi-fraction treatments (radiotherapy). If multi-fraction radiotherapy is applied the individually molded thermoplastic mask set ensures that for each fraction the patient is repositioned with the same position as in the initial setup.

3. **Substantial Equivalence**

When compared to its predicate device, the subject device remains same in terms of indications for use, the clinical condition, target user group, performance and safety characteristics, the principle of operation and the materials used.

Cranial patient immobilization via customized thermoplastic masks, which become flexible when heated up and are molded individually to the patient's head, is the technological principle for both the subject and predicate devices.

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

- Masks made from thermoplastic material
- Mask adjustment
- Fixation to CT/ treatment couch via an carbon-foam sandwich Overlay

The following technological differences exist between the subject and predicate devices:

- Subject offers additionally Open Face Mask and Basic Mask
- Mask attachment and adjustment via integrated clipping mechanism and spacers (subject device) vs. separate clips and spacers (predicate device)

The only change is that new mask sheet cuts are available which enable a wider scope of application and that the integrated mask attachment and height adjustment unit improve the usability by eliminating loose separate parts of the predicate device.

Conclusion

The changes described above do not alter intended use or the fundamental scientific technology of the device because they do not change the operating principle. The changes to the Subject Device do not present any new issues of safety and effectiveness when compared to the predicate device. Therefore, we believe that Subject Device and the predicate device is substantially equivalent, as demonstrated above.

4. Verification Activities

The following verification activities were carried out to ensure the safety and efficacy of the device.

- Tests according to applicable harmonized standards (methods as specified)
- Mechanical stability tests (according to applicable paragraphs of IEC 60601-1:2005 AMD 2012)
- Usability evaluations (according to EN 62366:2008)
- Reviews of Procedures (E-TAPs and Service manuals)
- Reviews of Documents, Drawings and Datasheets
- Tests according to applicable paragraphs of IEC 60601-1:2005 AMD 2012
- Compatibility / interface testing
- Dosimetry testing (dose build-up, dose attenuation)
- Biocompatibility testing acc. to ISO 10993-1: 2010