March 20, 2024

Brainlab AG
Esther Moreno Garcia
QM Consultant
Olof-Palme-Str.9
Munich, 81829
Germany

Re: K234047
Trade/Device Name: Automatic Registration
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 21, 2023
Received: December 21, 2023

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.

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,

Tejen D. Soni -S

For
Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic 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)*
K234047

Device Name
Automatic Registration

Indications for Use *(Describe)*
Automatic Registration is a software device for image guided surgery intended to be used in combination with compatible Brainlab navigation systems such as the Brainlab Spine & Trauma Navigation System. Automatic Registration provides an image registration for intraoperatively acquired 3D CT/CBCT or fluoroscopic images.

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
K234047

March 20, 2024

General Information

Manufacturer	Brainlab AG; Olof-Palme-Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Trade Name	Automatic Registration
Classification Name	Orthopedic Stereotaxic Instrument
Product Code	OLO
Regulation Number	882.4560
Regulatory Class	II
Panel	Orthopedic
Predicate Device(s)	K203679 - Automatic Registration

Contact Information

Primary Contact	Alternate Contact
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1. Indications for Use

Automatic Registration is a software device for image guided surgery intended to be used in combination with compatible Brainlab navigation systems such as the Brainlab Spine & Trauma Navigation System. Automatic Registration provides an image registration for intraoperatively acquired 3D CT/CBCT or fluoroscopic images.

2. Device Description

The Subject Device Automatic Registration is an accessory to the Brainlab Spine & Trauma Navigation System. It correlates intraoperatively acquired patient data (3D CT/CBCT or fluoroscopic images) to the surgical environment in order to provide a patient registration for subsequent use by the Brainlab Spine & Trauma Navigation application. The device includes the following software modules:

- Automatic Registration 2.6
- Universal Atlas Performer 6.0
- Universal Atlas Transfer Performer 6.0

And uses as well several hardware devices, mainly registration matrices, adhesive flat markers and a calibration phantom, for performing the registration. The software is installed on an Image

Guided Surgery (IGS) platform. The registration matrices are reusable devices, delivered non-sterile and having patient contact.

The image registration can be provided using different methods, depending on the compatible CT or Cone-Beam CT scanner used. There is a specific workflow integration with the 3rd party scanners Airo and LoopX, as well as a universal workflow that can be used with any CT scanner using Dicom data. As a new feature, Automatic Registration 2.6 implements the possibility to update an automatic registration generated with LoopX by using also a static (locked) AI/ ML algorithm provided by the Universal Atlas for detection of vertebrae in 2D X-Ray images. This vertebra detection is then used for a rough pre-positioning of 2D X-Rays in relation to the 3D dataset and reduces user interaction for outlining 2D images and manual pre-positioning of images.

3. Substantial Equivalence

For the Substantial Equivalence determination, comparison of the Subject Device features with the following predicate device(s) was carried out:

K203679 - Automatic Registration 2.5 (product code: OLO)

The predicate was chosen since it's the predecessor device and therefore very similar to the subject device w.r.t the indications for use, technological characteristics and use cases.

The main difference compared to the predicate device is the new Registration Update method using AI/ ML. The two already existing registration methods have been reimplemented in a new GUI, without significant changes.

Indications for use	Automatic Registration is a surgical device for image guided surgery intended to be used in combination with compatible Brainlab navigation systems. Automatic Registration provides an image registration for intraoperatively acquired 3D CT/ CBCT or fluoroscopic images. It consists of the software module Automatic Registration and hardware accessories.	Automatic Registration is a software device for image guided surgery intended to be used in combination with compatible Brainlab navigation systems such as the Brainlab Spine & Trauma Navigation System. Automatic Registration provides an image registration for intraoperatively acquired 3D CT/CBCT or fluoroscopic images.

Intended use environment	Automatic Registration is intended to be used in an OR environment. The device is not intended to be used in the MR environment..	Automatic Registration is intended to be used in an OR environment. The device is not intended to be used in the MR environment.
Software version	Automatic Registration 2.5	Automatic Registration 2.6 Universal Atlas Performer 6.0 Universal Atlas Transfer Performer 6.0
Hardware devices	• Registration Matrix CT – Open Surgery (Spine) • Registration Matrix CT – Small Incision (Spine) • Registration Matrix CT – Minimally Invasive (Cranial and Spine) • Adhesive flat markers • Calibration Phantom iCT	• Registration Matrix CT – Open Surgery (Spine) • Registration Matrix CT – Small Incision (Spine) • Registration Matrix CT – Minimally Invasive (Cranial and Spine) • Adhesive flat markers • Calibration Phantom iCT
Localization technique	Optical tracking	Optical tracking
Registration methods	• Universal AIR • Pre-Calibrated Automatic Registration	• Universal AIR • Pre-Calibrated Automatic Registration • Registration Update
Image registration accuracy	Registration accuracy of ≤ 2.5 mm (P95, i.e. within the 95th percentile) with a mean navigation accuracy with 3D deviation ≤ 1.5 mm.	Registration accuracy of ≤ 2.5 mm (P95, i.e. within the 95th percentile) with a mean navigation accuracy with 3D deviation ≤ 1.5 mm.
UI technology	WPF	HTML5
Compatible 3rd party CT scanners	CT and Cone Beam CT Imaging devices with DICOM Conformance Statement are compatible (Universal AIR). Airo and LoopX	CT and Cone Beam CT Imaging devices with DICOM Conformance Statement are compatible (Universal AIR). Airo and LoopX

4. Performance Data

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

Software Verification and Validation Testing

Software verification and validation testing has been conducted and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "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 submitted is for Enhanced Documentation level.

Bench Tests

- Accuracy: For the new registration method "Registration Update" the overall system registration accuracy was verified in human cadavers under a representative worst case scenario. The following acceptance criteria has been fulfilled: Registration accuracy of ≤ 2.5 mm (P95, i.e. within the 95th percentile) with a mean navigation accuracy with 3D deviation ≤ 1.5 mm. Therefore the subject device achieves the same accuracy values as the registration methods available in the predicate device.

- Machine Learning: The AI/ML algorithm used in the new registration method is a Convolutional Neural network (CNN) developed using a Supervised Learning approach. The algorithm was developed using a controlled internal process that defines activities from the inspection of input data to the training and verification of the algorithm. This is a static algorithm (locked). The assessment of the AI/ML detected landmarks on X-rays has been done by quantifying the object detection, the quality of vertebra level assignment, the quality of landmark predictions, and the performance of the observer view direction for 2D X-rays from the Universal Atlas Transfer Performer 6.0.

- Usability: Summative usability testing was performed in order to validate the new user interface and workflow guidance for the Registration Update method. The evaluation was conducted with 15 representative users which had to use the Registration Update under different circumstances. The summative usability testing identified no critical use related problems.

No clinical testing was required for the subject device.

5. Conclusion

The comparison of the Subject Device with the predicate device shows that Automatic Registration (2.6) 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.