March 18, 2021

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

Re: K203679
Trade/Device Name: Automatic Registration
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 12, 2021
Received: February 16, 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203679

Device Name
Automatic Registration

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

March 17, 2021

General Information	
Manufacturer	Brainlab AG
Establishment Registration	8043933
Device Name	Orthopedic Stereotaxic Instrument
Trade Name	Automatic Registration
Classification Name	Stereotaxic instrument
Product Code	OLO
Regulation Number	882.4560
Regulatory Class	II
Panel	Orthopedic
Predicate Device and K Number	Spine & Trauma Navigation System - K183605
Manufacturer	Brainlab AG

Contact Information	
Primary Contact	**Alternate Contact**
Chiara Cunico Manager RA Phone: +49 89 99 15 68 0 Email: chiara.cunico@brainlab.com	Regulatory Affairs Brainlab Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 5033 Email: regulatory.affairs@brainlab.com

1. 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.

2. Device Description

The Subject Device is 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 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.

In a spinal context, Automatic Registration serves as accessory to the Spine & Trauma navigation system.

The Matrices are reusable devices delivered in non-sterile condition. The devices makes the Correlation ("Registration") of Intraoperative acquired patient data to the surgical environment possible by determining its position in relation to the patient and the navigated instruments.

3. Substantial Equivalence

Devices	Name	K-Number	Manufacturer
Subject Device	Automatic Registration	K203679	Brainlab AG
Predicate Device	Spine & Trauma Navigation System	K183605	Brainlab AG

Feature / Topic	Area	Changes of *Automatic Registration* in relation to the predicate device K183605
Indications for use	General	Same as in predicate device; minor expansion for automatic registration specific feature
Integration of Brainlab IGS (computer) platforms	Compatibilities and Hardware Components	Same basic functionality; added compatibility to a platform with minor differences
Automatic Image Registration	Compatibilities to external imaging devices	Same basic functionality; further compatibilities added with minor differences Compatibility was added for a new intraoperative 3D imaging device for pre-calibration.
Instruments that can be employed – Navigation Accessories	Compatible Instruments and software relevant Hardware	Addition of hardware parts with minor differences. Same principle in registration of 2D and 3D images. Material and design adapted to fit requirements of Universal AIR (Registration Matrix)

Feature / Topic	Area	Changes of *Automatic Registration* in relation to the predicate device K183605
Automatic patient registration	Software relevant behavior and features	Same basic functionality; minor modifications in GUI/functionality. The main functionality components of the software system stay the same. Additional instructions were added for automatic patient registration using Universal AIR. Icons and graphical representations of scanner reference arrays were added to visualize the additionally integrated scanning devices. The basic concept of verification of registration accuracy prior to navigation remains unchanged.

Non-Clinical Testing:

1. Registration Accuracy Test
   Test Result:

   - Mean navigation accuracy: 0.93mm
   - 95th percentile of single navigation accuracy: 1.80mm
   - Total number of navigation points n=228

Above listed non-clinical performance testing demonstrates the equivalence of the navigation registration accuracy of the subject device to the predicate device. It was performed in a simulated test environment which matches the test scenario of the cleared device, where a mean registration accuracy of 1.26mm was measured.

Minor modifications to the test setup were required due to the device change where a Registration Matrix within the scan volume is used for automatic registration instead of infrared scanner markers in combination with a navigation calibration as in the cleared device. The navigated region of interest and measurement methods were not changed since these parameters are not affected by the device change.

An additional performance test demonstrated that the registration method is also applicable for the cervical spine and navigation accuracy in this region is consistent with the initial results listed above.

Test results generated demonstrated better mean navigation accuracy and met stricter acceptance criteria (mean navigation accuracy: <=1.5mm, 95th percentile of single navigation accuracy: <=2.5mm) compared to the predicate device (mean navigation accuracy: <=2.0mm; 95th percentile of single navigation accuracy: <=3.0mm). The total number of measured navigation points (n=228) and total number of scans used (m=50) were increased compared to performance testing of the predicate device (n=126; total number of scans used: m=32).

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. Non-clinical performance tests demonstrated that device changes do not negatively affect registration accuracy. The changes to the Subject Device do not present new issues of safety and effectiveness when compared to the predicate device while still providing the benefit of an equally accurate registration resulting in an unchanged risk benefit ratio. Therefore, the devices are substantially equivalent.