May 16, 2025

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

Re: K242569
Trade/Device Name: Mixed Reality Spine Navigation
Regulation Number: 21 CFR 882.4560
Regulation Name: Augmented Reality Stereotaxic Instrument
Regulatory Class: Class II
Product Code: SBF
Dated: August 28, 2024
Received: May 12, 2025

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,

Shumaya Ali -S

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)*
K242569

Device Name
Mixed Reality Spine Navigation

Indications for Use *(Describe)*
Mixed Reality Spine Navigation is an accessory to the Spine & Trauma Navigation Medical Device. The software is intended to display 2D navigation screens as well as a floating 3D virtual representation and stereotaxic information of tracked instruments on a virtual display using a Mixed Reality headset. The virtual display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed stereotaxic information.

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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BRAINLAB

510(k) Summary - K242569

May 15, 2025

General Information

Manufacturer	Brainlab AG; Olof-Palme-Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Trade Name	Mixed Reality Spine Navigation
Classification Name	Augmented Reality Stereotaxic Instrument
Product Code	SBF
Regulation Number	882.4560
Regulatory Class	II
Panel	Orthopedic
Predicate Device	K221618 - Spine & Trauma Navigation
Reference Device	K223290, CommandEP Data Manager PC (DPC02), CommandEP HMD (HMD02)

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 Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 5033 Email: chiara.cunico@brainlab.com

1. Indications for Use

Mixed Reality Spine Navigation is an accessory to the Spine & Trauma Navigation Medical Device. The software is intended to display 2D navigation screens as well as a floating 3D virtual representation and stereotactic information of tracked instruments on a virtual display using a Mixed Reality headset. The virtual display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed stereotaxic information.

2. Device Description

The Subject device Mixed Reality Spine Navigation is an accessory to the Spine & Trauma Navigation System. It consists of the software Mixed Reality Spine Navigation 1.0 and the mixed reality headset Magic Leap 2 Medtech (ML2). The software application allows the display in the mixed reality headset of 2D navigation views and a 3D hovering model of the patient anatomy, including stereotactic information of tracked instruments to support the surgeon during pedicle screw placement procedures.

The software Mixed Reality Spine Navigation is installed and running on the Magic Leap 2 MedTech glasses and can only be used in combination with a Brainlab Image Guided Surgery (IGS) platform (Curve Navigation 17700, Kick 2 Navigation Station or Buzz Navigation Ceiling-Mounted), where the Spine & Trauma Navigation software is running. All required navigation

data, such as the patient registration, is transferred over Wi-Fi from the IGS platform to the Magic Leap 2 MedTech. Based on these data, 2D views and a 3D model are rendered by the computing unit of the Magic Leap 2 MedTech and displayed stereoscopically in the headset. Thus, navigation information displayed on the screen(s) of the IGS platform can be simultaneously displayed on Magic Leap 2 MedTech during the surgery.

Magic Leap 2 MedTech is an optical see-through head-mounted display: images are projected on semi-transparent optical layers, giving the surgeons the possibility to have virtual content displayed around the patient while having a view of the real world. If needed, corrective lenses can be attached to the headset.

3. Substantial Equivalence

For the Substantial Equivalence determination, comparison of the Subject Device features with the following predicate device and reference device was carried out:

K221618 - Spine & Trauma Navigation (product code: OLO)
K223290, CommandEP Data Manager PC (DPC02), CommandEP HMD (HMD02) (product code: LLZ)

The predicate device was chosen since both the subject device and the predicate are used together and have similar technological characteristics and use case. The reference device was chosen for comparison basis of the Magic Leap 2 Medtech glasses.

The main difference compared to the predicate device is the use of the Magic Leap 2 Medtech headset allowing to view 2D and 3D views in the proximity of the patient ´s anatomy.

Feature	Predicate Device K221618	Reference Device K223290	Subject Device
Indications for use	Spine & Trauma Navigation is intended as an intraoperative image-guided localization system to enable open and minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or Intraoperative 2D or 3D image data. Spine & Trauma Navigation enables computer assisted navigation of medical image data, which can either be acquired preoperatively or intraoperatively by an appropriate image acquisition system. The software offers screw and interbody device planning and navigation with surgical instruments. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 3D fluoroscopic image reconstruction or	N/A	Mixed Reality Spine Navigation is an accessory to the Spine & Trauma Navigation Medical Device. The software is intended to display 2D navigation screens as well as a floating 3D virtual representation and stereotactic information of tracked instruments on a virtual display using a Mixed Reality headset. Similar to predicate device. The subject device provides another way of displaying navigation information for spine screw placement procedures.

Feature	Predicate Device K221618	Reference Device K223290	Subject Device
	2D fluoroscopic image) and/or an image data based model of the anatomy.		
Intended use environment	The navigation system shall be used in an operating room / suite. The navigation system is not intended to be used inside an MR environment.	N/A	The intended use environment is the operating room. The device is not intended to be used in the MR environment. Pre- and/or intraoperative MR imaging is not part of the clinical workflows for which the device is used. Same as predicate device.
Software version	Spine & Trauma Navigation 2.0	N/A	Mixed Reality Spine Navigation 1.0 Spine & Trauma Navigation 2.0
Mixed Reality Headset	N/A, no Magic leap 2 available	CommandEP HMD (Magic Leap 2 glasses): - Includes headset, compute pack and controller. - Possible to connect simultaneously up to five headsets - Provided non-sterile	Magic Leap 2 Medtech: - Includes headset, compute pack and controller. Additionally it comes with a backpack for carrying the compute pack under the sterile gown and possibility of prescription lenses. - Possible to connect simultaneously up to four headsets - Provided non-sterile

Feature	Predicate Device K221618	Reference Device K223290	Subject Device
			Similar to reference device.
Date transfer between mixed reality headset and platform	N/A, no Magic leap 2 available	Encrypted wireless transfer (Wi Fi)	Encrypted wireless transfer (Wi-Fi). Identical to reference device. Same as reference device.
User interaction	Touch screen of IGS platform and remote control	CommandEP HMD (Magic Leap 2 MedTech: Hands-free gaze-dwell controls (the use of the controller is not required).	<u>IGS platforms:</u> Touch screen and Remote Control <u>Magic Leap 2 MedTech:</u> Gesture controls (the use of the controller is not required). Same as predicate for interaction with IGS platform and similar to reference device. User interface and gesture controls have been validated during usability testing.
Localization technique	Optical tracking	N/A	Optical tracking. Same as predicate device.
Navigation accuracy	• Mean Positional Error of the placed instrument's tip ≤ 2 mm • Mean Angular Error of the placed instrument's axis ≤ 2°	N/A	• Mean Positional Error of the placed instrument's tip ≤ 2 mm • Mean Angular Error of the placed instrument's axis ≤ 2° Same as predicate device.

Feature	Predicate Device K221618	Reference Device K223290	Subject Device
View features	Inline views for navigation, 3Ds views, Probe ´s eye view, autopilot and DDR view.	N/A	All views displayed in the IGS platforms screen of the predicate can also be displayed when using the subject device. With the Magic Leap 2 Medtech, two additional views (virtual displays) are available: 2D floating display with Probe ´s eye and trajectory displays and a 3D floating model. Similar to predicate device, same views available (except for DRR and autopilot views) and additional floating views in the proximity of the patient anatomy.
Intra-operative planning of implants	Views and features to enable intraoperative planning of implants	N/A	Spine &Trauma Navigation software is also running in the IGS platform when using Mixed Reality Spine Navigation, thus same views and features as predicate device for intraoperative planning of screws. In addition, planned screws and trajectories can also be displayed in 2D and 3D views in the ML2 Medtech.
GUI technology	HTML5	N/A	Mixed Reality Toolkit

Feature	Predicate Device K221618	Reference Device K223290	Subject Device
			Similar to predicate device. Same GUI style implemented with a different technology.
IGS platforms	Curve Navigation 17700 Kick 2 Navigation Station (several models) Buzz Navigation (Ceiling-Mounted) Curve 1.1/1.2 Navigation Station	N/A	Curve Navigation 17700 (several models) Kick 2 Navigation Station (several models) Buzz Navigation (Ceiling-Mounted) Curve 1.1/1.2 Navigation Station An additional Curve Navigation platform #17701 has been introduced, remaining platforms are the same as predicate device.

4. Performance Data

The following testing was conducted on the Subject Device to establish substantial equivalence with the predicate device. Test methods are equivalent to the predicate and reference devices.

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.

Hardware verification

- For basic safety and EMC, testing was provided according to IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION and IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION.
- Biocompatibility evaluation was carried out in accordance with ISO 10993-1: 2018.
- Cleaning validation in accordance with FDA ´s guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".
- Testing in accordance with IEC 63145-20-10:2019 / 63145-20-20:2019 / 63145-22-10:2020, applicable to Eyewear displays, was provided in order to assess optical properties such as luminance or chromaticity.

Bench Tests

- Usability testing was provided to validate the pedicle screw placement workflow using Mixed Reality Spine Navigation in a simulated OR environment.
- Network performance benchmarking has been performed to ensure that Mixed Reality Spine Navigation is working as intended with minimum bandwidth requirements.

No clinical testing was required for the subject device.

5. Conclusion

The comparison of the Subject Device with the predicate device shows that Mixed Reality Spine Navigation (1.0) 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.