September 12, 2025

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

Re: K252562
Trade/Device Name: Spine & Trauma Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 14, 2025
Received: August 14, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252562

Device Name
Spine & Trauma Navigation Instruments

Indications for Use *(Describe)*
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 2D fluoroscopic image) and/or an image data based model of the anatomy.

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

August 14th, 2025

General Information

Manufacturer	Brainlab AG; Olof-Palme-Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Trade Name	Spine & Trauma Navigation Instruments
Classification Name	Orthopedic Stereotaxic Instrument
Product Code	OLO
Regulation Number	882.4560
Regulatory Class	II
Panel	Orthopedic
Predicate Device(s)	K221618 - Spine & Trauma Navigation

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

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 2D fluoroscopic image) and/or an image data based model of the anatomy.

2. Device Description

The Spine & Trauma Navigation is an image guided surgery system for navigated treatments in the fields of spine and trauma surgery, whereas the user may use image data based on CT, MR, 3D fluoroscopic image reconstruction (cone beam CT) or 2D fluoroscopic images. It offers

different patient image registration methods and instrument calibrations to allow surgical navigation by using optical tracking technology. To fulfil this purpose, it consists of software, Image Guided Surgery platforms and surgical instruments.

Brainlab ´s spinal instrument portfolio includes common types of instruments used in image guided surgery procedures including patient referencing instruments, instruments for image registration, drill guides, drill bits, tracking arrays, awls and probes for open surgery, Starlink instrument adapters and arrays to allow the connection of suitable 3rd party instruments, an Instrument Calibration Matrix for calibration of instruments, sets of instruments to be used with the accessories Microscope Navigation and Cirq Arm System, the sterile instruments Disposable Trocar Insert Pedicle Access Needle and Disposable Clip-On Remote Control and Sterilization Trays.

Modified spine reference clamps and Sterilization Trays have been introduced as part of the Subject Device. The new Patient Reference Rod-Clamp Spine & Trauma belongs to the Patient Reference Clamp Spine & Trauma group, consisting of 3 clamps, two intended to achieve a rigid fixation to the bone and a third one intended to achieve rigid fixation to a rod. This provides a solid interface for stiff reference array fixation, enabling navigated surgery with the Spine & Trauma Navigation software. The novel feature is the possibility to attach the clamp to an existing rod, which is only possible with the Patient Reference Rod-Clamp Spine & Trauma. All clamps are delivered unsterile and require end user sterilization.

The Sterilization Trays serve as a rigid containment device intended for the repeated use before, during and after sterilization in healthcare facilities to store, organize, identify and transport a set of specified instruments, which require sterilization prior to use. The Sterilization Tray requires an additional sterile barrier system to maintain sterile. There are multiple variants of the Sterilization Trays, each offering designated slots and outlines to a defined set of compatible instruments.

3. Substantial Equivalence

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

K221618 - Spine & Trauma Navigation (product code: OLO)

The predicate device 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 are modified instruments.

Feature	Predicate Device K221618	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 2D fluoroscopic image) and/or an image databased model of the anatomy.	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 2D fluoroscopic image) and/or an image databased model of the anatomy.
Navigation accuracy	Mean Positional Error of the placed instrument's tip ≤ 2 mm Mean Angular Error of the placed instrument's axis ≤ 2°	Mean Positional Error of the placed instrument's tip ≤ 2 mm Mean Angular Error of the placed instrument's axis ≤ 2°
Tracking technology	Optical tracking	Optical tracking
Patient Reference Clamps		
Overview Patient	Spine Reference Clamp Carbon Spine Reference X-Clamp Size S Spine Reference X-Clamp Size L	Spine Reference Clamp Carbon, same as predicate device.

Feature	Predicate Device K221618	Subject Device
Reference Clamps		X-Clamps sizes S and L are end of sales. Patient Reference Rod-Clamp Spine & Trauma Patient Reference Steel-Clamp Spine & Trauma Size S Patient Reference Steel-Clamp Spine & Trauma Size L New set of clamps with improved stiffness.
Principle of operation	Rigid fixation to the bone by clamping the bone between two clamp arms, that have bone pins which penetrate through remaining tissue into cortical bone.	Patient Reference Rod-Clamp Spine & Trauma: Rigid fixation to the bone indirectly, by clamping onto a rod which is attached to the bone by pedicle screws. The clamp is attached to the rod by means of a hook-clamp mechanism. Patient Reference Steel-Clamp Spine & Trauma Size S and L: Same fixation concept to bone as in predicate device.
Sterility	Provided non-sterile End user steam sterilization Reusable	Provided non-sterile End user steam sterilization Reusable
Patient contacting materials	Stainless steel and PEEK	Stainless steel and PEEK
Sterilization Trays		
Classification	Compatible Sterilization Trays considered class I exempt with code FSM.	Classified as class II with code OLO.
Tray Variants	Multiple variants of Sterilization Trays available.	For existing trays no changes other than the classification. Two new variants of Sterilization Trays were introduced to accommodate new instruments. Overall design remains very similar to predicate device since all trays are based on the same generic concept from the same supplier.

Feature	Predicate Device K221618	Subject Device
Sterility	Provided non-sterile End user steam sterilization Reusable	Provided non-sterile End user steam sterilization Reusable
Patient contact	None	None

4. Performance Data

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

For Patient Reference Rod-Clamp Spine & Trauma:

- Mechanical stability throughout the defined lifetime, by assessing the influence of wear under simulated use.
- Fixation stability of the clamp against static and dynamic loads, which proved to be equal or better as the predecessor clamps.
- Reprocessing: The Patient Reference Rod-Clamp Spine & Trauma requires automatic cleaning including an ultrasonic bath and end user sterilization before use. A worst case comparison was performed against representative tested devices.
- Biocompatibility: Was evaluated according to ISO 10993-1:2018 “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” for a device with contact with tissue and blood for a limited time (<24h).
- Usability: A formative usability was carried out for the new design of the rod clamp, which proved to be safe and effective.

For the Sterilization Trays:

- Mechanical stability has been verified for a worst case device, since the mechanical parts, user interfaces and materials are identical across sterilization tray variants. Testing also included variant specific tests to ensure the compatible instruments fit in the designated trays.
- Biocompatibility: Even though the Sterilization Trays have no intended body contact acc. to ISO 10993-1, the used materials were assessed with regard to their possible influence on the biocompatibility of the stored surgical instruments. No further risk was discovered.
- Reprocessing: The trays have been validated for recommended cleaning and disinfection methods as well as for steam sterilization and drying in combination with a rigid sterile barrier systems, following a worst case comparison as proposed in ISO 17664-1.

No clinical testing was required for the subject device.

5. Conclusion

The comparison of the Subject Device with the predicate device shows that the modified Spine & Trauma Navigation including modified instruments 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.