August 30, 2022

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

Re: K221618
Trade/Device Name: Spine & Trauma Navigation, Spine Navigation, Navigation Software Spine & Trauma, Alignment System Spine, Alignment Software Spine, Cirq Arm System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 31, 2022
Received: June 3, 2022

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221618

Device Name
Spine & Trauma Navigation, Navigation Software Spine & Trauma, Spine Navigation Alignment System Spine, Alignment Software Spine, Cirq Arm System

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 databased model of the anatomy.

As an accessory to the Spine & Trauma Navigation, the Alignment System Spine is intended to support the surgeon to achieve a pre-defined screw with surgical instruments during the surgical procedure. It is used for spinal screw placement procedures.

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.

510(k) Summary

August 30, 2022

General Information	
Manufacturer	Brainlab AG; Olof-Palme-Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Trade Name	Spine & Trauma Navigation Navigation Software Spine & Trauma Spine Navigation Alignment System Spine Alignment Software Spine Cirq Arm System
Classification Name	Orthopedic Stereotaxic Instrument
Product Code	OLO
Regulation Number	882.4560
Regulatory Class	Class II
Panel	Orthopedic
Predicate Device(s)	Primary Predicate: K212245 Spine & Trauma Navigation System Secondary Predicate: K110204 Brainlab Trauma Third Predicate: K202320 Cirq Robotic Alignment Module

Contact Information	
Primary Contact	**Alternate Contact**
Chiara Cunico Manager Regulatory Affairs Phone: +49 89 99 15 68 0 Email: regulatory.affairs@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. Indication for Use

Spine & Trauma Navigation

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.

Alignment System Spine

As an accessory to the Spine & Trauma Navigation, the Alignment System Spine is intended to support the surgeon to achieve a pre-defined screw with surgical instruments during the surgical procedure. It is used for spinal screw placement procedures.

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 coming from the compatible imaging device LoopX. It offers different patient image registration methods and instrument selection and calibration to allow surgical navigation by using optical tracking technology.

The software is installed on a mobile or fixed Image Guided Surgery (IGS) platform to support the surgeon in clinical procedures by displaying tracked instruments in patient's image data. The IGS platforms comprise of a mobile Monitor Cart or a fixed ceiling mounted display and an infrared camera for image guided surgery purposes.

The Spine &Trauma Navigation consists of the following components:

- Software enabling instrument selection, different registration methods (e.g. surface matching) as well as navigation in different types of images.
- IGS platforms
- Surgical instruments for navigation, patient referencing and registration

The *Alignment System Spine* is an accessory to the Spine & Trauma Navigation. It serves as a holding and positioning system to support the surgeon in reaching a pre-defined screw with surgical instruments. The device needs to be first manually pre-aligned to the region of interest by opening the brakes of the Cirq Arm System. Then tracking information provided by the optical camera is used by the Alignment Software Spine 2.0 to control the movement of the Cirq Robotic Motor Unit to perform the final automatic fine alignment. Once the alignment to the planned screw is done, the Alignment System Spine maintains its position during the rest of the procedure and Spine & Trauma 3D Navigation takes over the navigation of the instruments. The Alignment System Spine consists of the following components:

- Alignment Software Spine 2.0
- Cirq Arm System with multiple structural hardware components
- Cirq Robotic Motor Unit
- Cirq robotic instruments

The operator's profile for the Subject Device are Neuro / Ortho / Spine / Trauma surgeons or their assistants having a 3D image acquisition system (such as a CT or a 3D C-arm),or utilizing preoperatively acquired CT / CT-like (and potentially fused MR) imaging data in combination with a Brainlab navigation.

3. Substantial Equivalence

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Item	Predicate device	Product Code	New/modified device
1st Predicate:	Spine & Trauma Navigation System (K212245)	OLO	Spine & Trauma Navigation 2.0
2nd Predicate	Brainlab Trauma (K110204)	OLO	Spine & Trauma Navigation (specifically for Fluoro Navigation 1.0)
3rd Predicate	Cirq Robotic Alignment Module (K202320)	OLO	Alignment System Spine

At a high level, the main similarities and differences between the subject and predicate devices are:

For Spine &Trauma Navigation:

Same or similar aspects	Differences
• Indications for use • Localization technology: Optical • System accuracy in 2D and 3D images • Registration and calibration of instruments • Supported image modalities • Supported IGS platforms • Surgical instruments • Programming language	• GUI technology • Main functionality is the same, but tools and view layouts are organized slightly differently • Compared to K212245: Integrated interface to the Alignment System Spine • Compared to K110204: Fluoro Navigation supports only 2D images from the compatible imaging device LoopX and different registration method

For Alignment System Spine:

Same or similar aspects	Differences
• Indications for use	• GUI technology

• Guided positioning: manual alignment followed by an automatic alignment • Robotic movement • Same positioning arm and hardware components • Same instruments • Localization technology: Optical • Supported IGS platforms	• The functionality to calibrate and navigate instruments has been removed and is now performed with Spine & Trauma Navigation • Integrated interface to the Spine & Trauma Navigation

4. Performance Data

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

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern.

Hardware verification

Hardware verification was carried out to ensure all requirements for the platforms are met. It was also ensured that the platforms are able to work as intended during their defined lifetime by performing endurance testing, the safety of the cleaning and disinfection process and the biological safety of the materials and surfaces which may become in contact with the user.

System accuracy testing

The 2D and 3D positional and angular navigation accuracy of the Spine &Trauma Navigation including the software, the platforms and the instruments was evaluated considering a realistic clinical setup and representative worst-case scenarios. The results show the following acceptance criteria are fulfilled:

- Mean Positional Error of the placed instrument's tip ≤ 2 mm
- Mean Angular Error of the placed instrument's axis ≤ 2°

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety, RFID and EMC testing was conducted on the Subject device according to the standards:

IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance. Including US national deviations.

AIM 7351731 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers.

IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

No clinical testing was needed for the Subject Device.

5. Conclusion

The comparison of the Subject Device with the predicate devices shows that the Spine & Trauma Navigation and its accessory the Alignment System Spine have similar functionality, intended use and technological characteristics as the predicate device(s). Based on the comparison to the predicates and the performance testing conducted, the Subject Device is considered substantially equivalent to the predicate devices.