May 23, 2024

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

Re: K240701
Trade/Device Name: Drill Guide; Drill Bit; Spine & Trauma Navigation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 14, 2024
Received: April 23, 2024

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)*
K240701

Device Name
Drill Guide; Drill Bit; Spine & Trauma Navigation

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.

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

March 14th, 2024

General Information

Manufacturer	Brainlab AG; Olof-Palme-Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Trade Name	Drill Guide Drill Bit Spine & Trauma Navigation
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
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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 databased 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.

Modified Drill Guides and Drill Bits have been introduced as part of the Subject Device. The Drill Guide instruments are navigated instruments which support the surgeon in guiding drill bits and K-wires during spinal procedures. They consist of a guide tube, a trocar insert (both available in five different diameters), a body with two available handles, an array and a depth control (available in two different sizes for various drilling depths). The Drill Guide Tubes and Drill Guide Trocar Inserts have patient contact. All instruments are delivered unsterile and require end user sterilization.

The Drill Bits are used for drilling of bone. They are made of stainless steel and are delivered non-sterile. They require steam sterilization onsite before use. There are several variants in terms of diameter, length, and presence of a depth stop feature.

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	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

Feature	Predicate Device K221618	Subject Device
	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.	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
Drill guide components	-Drill Guide Handles -Drill Guide Compact Handle -Drill Guide Tubes -Drill Guide Trocars -Tissue Protection Sleeve -Drill Guide Depth Controls	-Drill Guide Handle -Drill Guide Handle Compact -Drill Guide Tubes -Drill Guide Trocar Inserts -Drill Guide Depth Controls -Drill Guide Array
Adjustment and handling features of Drill Guides	• Adjusting position of handle requires loosening of the counter nut. • Array is fixed to the handle body • The guide tubes are attached to the main drill guide body by means of a left-handed thread. • Depth control is attached to drill guide body by a thread and	• Rotatable handle allows to adjust position relative to array without loosening any fixation elements. • Detachable array with integrated magnet to prevent it from dropping.

Feature	Predicate Device K221618	Subject Device
	depth setting is secured with a counter nut.	• The Guide Tube is attached to the Handle by simple linear insertion and held in place by a click interface. • Depth control is attached and depth setting is secured with a snapping mechanism.
Drill Bits	Drill bits with diameters between 2.4mm to 4.5mm.	Four new drill bits are introduced, three within the same range of diameters (3.2 and 4.5mm). A new worst case drill bit with a diameter of 2mm.
Cleaning and sterilization	Automated cleaning and automated thermal disinfection Steam sterilization	Automated cleaning and automated thermal disinfection Steam sterilization

4. Performance Data

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

- **Assembly stability**: In order to verify that the stiffness and fixation of the instruments can resist unintended loads. The Drill Guide was able to withstand the forces without losing accuracy or function.

- **Accuracy**: Accuracy testing was performed with acceptance criteria: tip position deviation must be equal or below 1.7 mm (95th percentile), and the angular deviation must be equal or below 1.7° (95th percentile). Testing showed the modified Drill Guide fulfills the same accuracy requirements as the predecessor one.

- **Lifecyle assessment**: To evaluate the influence of wear, reprocessing and aging on selected aspects of product performance throughout the product lifetime. Accuracy as well as label readability requirements were met.

- **Skiving**: Skiving testing showed the modified Drill Guide provides a more stable hold with the improved teeth design compared to the predicate Guide Tubes.

- **Handling and interface analysis**: The Drill Guide design changes in terms of depth control and array attachment concept were evaluated and acceptance criteria were met in all cases.

- **Usability**: Summative usability testing was performed in order to validate the changed design of the Drill Guides. The evaluation was conducted with 15 representative users

which had to assemble and use the Drill Guide in a simulated scenario. The final design was proven safe and effective for use in the defined use scenarios.

- **Mechanical failure testing:** The new worst case drill bit (diameter 2 mm) was tested under different scenarios in order to ensure it is strong enough to withstand the expected torques and possible bending under worst case conditions.

- **Biocompatibility:** Was evaluated according to ISO 10993-1:2018 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

- **Reprocessing validation:** Was evaluated according to ISO 11737-1:2018, ANSI/AAMI ST98:2022 and ISO 15883-5:2021-07.

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.