April 13, 2022

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

Re: K212245
Trade/Device Name: Spine & Trauma Navigation System, Spine & Trauma 3D Navigation, Navigation Software Spine& Trauma 3D, Elements Screw Planning Spine, Elements Spine Screw Planning, Spine Planning

Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 10, 2022
Received: March 14, 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)*
K212245

Device Name
- Spine & Trauma Navigation System
- Spine & Trauma 3D Navigation, Navigation Software Spine & Trauma 3D
- Elements Screw Planning Spine, Elements Spine Screw Planning, Spine Planning

Indications for Use *(Describe)*

Spine & Trauma Navigation System

Spine & Trauma Navigation System 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 System 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, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.

Spine Planning

Spine Planning is intended for pre- and intraoperative planning of open- and minimal invasive spinal procedures. It displays digital bio imaging and allows measurement and planning of spinal implants like screws and rods.

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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510(k) Summary

March 10, 2022

General Information	
Manufacturer	Brainlab AG; Olof-Palme Str.9; 81829, Munich, Germany
Establishment Registration	8043933
Device Name	Orthopedic Stereotaxic Instrument
Trade Name	• Spine & Trauma Navigation System • Spine & Trauma 3D Navigation, Navigation Software Spine & Trauma 3D • Elements Screw Planning Spine, Elements Spine Screw Planning, Spine Planning
Product Code	OLO
Regulation Number	882.4560
Regulatory Class	II
Panel	Orthopedic
Predicate Devices	Primary: Spine & Trauma Navigation K183605 Secondary: : Medtronic StealthStation S8 Spine Software v1.0.0; K170011

Contact Information	
Primary Contact	**Alternate Contact**
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1. Indications for Use

Spine & Trauma Navigation System 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.

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, along bone or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.

Spine & Trauma 3D Navigation

Spine & Trauma 3D 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.

Spine Planning

Spine Planning is intended for pre- and intraoperative planning of open- and minimal invasive spinal procedures. It displays digital bio imaging and allows measurement and planning of spinal implants like screws and rods.

2. Device Description

The Subject Device Spine and Trauma Navigation System consists of the following software's and hardware.

Software:

1. Spine & Trauma 3D Navigation 1.5
   Spine & Trauma 3D Navigation enables navigation of instruments using the Spine & Trauma Navigation System.
   Instruments that were calibrated in Instrument Selection are loaded for use with Spine & Trauma 3D Navigation.

2. Instrument Selection 1.6
   This software lists all the available instruments listing them by manufacturer, type, description and article number.
   The software offers functionality to select and activate navigated surgical instruments that are provided to Spine & Trauma 3D Navigation and other software components.

3. Fluoro 3D 1.0
   Registration Software Fluoro 3D enables registration of patient scans in the Spine & Trauma Navigation System.
   This software establishes compatibility to integrated 3rd party 3D-Fluoroscopes.
   Dedicated hardware accessories allocate the fluoroscope during image acquisition. Each image acquisition in registration mode delivers registered images in 3D of the patient anatomy.

4. Registration Software Paired Point 3.5
   Registration Software Paired Point is a touchscreen-based intraoperative registration software.
   The placement of surgical instruments in a three-dimensional representation overlaid on anatomical image sets, such as CT and/or XT, can support the surgeon during various surgical interventions.

   Registration Software Paired Point is used to register the patient position relative to the preoperative or intraoperative scans prior to surgical navigation.

   The following registration points are possible:
   • Anatomical landmarks
   • Screws

5. Registration Software Spine Surface Matching 1.0
   Registration Software Spine Surface Matching is a touchscreen-based intraoperative registration software. The placement of surgical instruments in a three-dimensional representation overlaid on anatomical image sets, such as CT and/or XT can support the surgeon during various surgical interventions.

Registration Software Spine Surface Matching is used to register the patient position relative to the preoperative scans prior to surgical navigation.

6. Spine Planning 1.0
   Brainlab Elements Spine Planning allows planning of screws for surgical navigation. Depending on the region of interest, screws can be automatically proposed by the software or planned manually. These screws must be reviewed and approved before proceeding with navigated surgery.

Hardware:

The Hardware accessories for the Subject Device are Platforms and Surgical Instruments.

3. Substantial Equivalence

The Subject Device is similar to the predicate devices in terms of:

a. Interbody instrument navigation: Accuracy
b. Interbody instrument navigation: Imaging modalities
c. Interbody instrument navigation: View (Display) Features
d. Localization Technology
e. Programming language
f. Graphical User Interface
g. Improved instrument activation methods
h. Intra-operative planning of implants
i. Automatic patient registration
j. Manual Registration
k. Implant planning
l. Additional compatibility to modified hardware components and instruments or accessories

The Subject Device differs from its predicate devices in terms of:

m. Interbody instrument navigation: new instrument activation methods introduced
n. Architecture: added compatibility to new software modules
o. GUI technology
p. Added additional platform compatibility
q. Added compatibility to instruments from 3rd party manufacturers

4. Performance Data

The verification of the Spine & Trauma Navigation System has been carried out thoroughly both at the top level and on underlying modules according to the verification plan and following internal processes. The verification was done to demonstrate that the design specifications are met.

In general, verification includes different kinds of tests like Unit Tests within the software, GUI based automatic software tests and explorative testing. Results are documented in corresponding test reports and summarized in the Verification Summary document. For hardware parts, mechanical or biocompatibility tests were performed and filed accordingly.

Electrical safety and electromagnetic compatibility (EMC)

N/A as no EMC considerations are within the scope of this 510(k).

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.

Biocompatibility and Reprocessing

Material properties in relation to biocompatibility and their response to cleaning, disinfection and sterilization were assessed and tested.

Bench Testing

The following tests were conducted for the instruments and all test were passed successfully.

- Array Radiolucent Cervical Clamp Stability Vibration Resistance Test
- Radiolucent Cervical Clamp Fixation Stability Test
- Array Radiolucent Cervical Clamp Fixation Stability Test
- Instrument Adapter Extension - Slip Resistance Test

5. Conclusion

The comparison of the Spine & Trauma Navigation System with the predicate device shows that the Spine & Trauma Navigation System has similar functionality, intended use, technological characteristics, and typical users as the predicate devices. Other included minor changes do not affect the fundamental scientific technology of the device.
Verification and validation activities ensure that the design specifications are met and that the Spine & Trauma Navigation System does not introduce new issues concerning safety and effectiveness. Hence, the Spine & Trauma Navigation System is substantially equivalent to the predicate devices.