Brainlab AG
Julia Mehltretter
Manager Product Surveillance
Olof-Palme-Str. 9
Munich, 81829 De

June 11, 2019

Re: K191285
Trade/Device Name: Spine & Trauma Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 10, 2019
Received: May 13, 2019

Dear Julia Mehltretter:

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, MPH
Assistant Director
DHT6C: Division of Stereotaxic, Trauma
and Restorative 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191285

Device Name
Spine & Trauma Navigation System

Indications for Use *(Describe)*
Spine & Trauma Navigation System is intended as an intraoperative image-guided localization system to enable 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 implant size planning and navigation on rigid bone structures with precalibrated and additional individually-calibrated surgical tools.
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.

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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K191285

SPECIAL 510(K) CORRECTIVE ACTION BEING EFFECTED SUMMARY

SPINE & TRAUMA NAVIGATION SYSTEM

IN ACCORDANCE WITH REQUIREMENTS OF 21 CFR PART 807.92

Manufacturer:	Brainlab AG Olof-Palme-Str. 9 81829 Munich Germany Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 5033
Submitter:	Rainer Birkenbach
Contact person:	Julia Mehltretter
Summary date:	6/11/2019
Device:	Spine & Trauma Navigation System
Trade name:	Spine & Trauma 3D
Common Name:	Brainlab Image Guided Surgery System / Instrument, Stereotaxic
Device Classification Regulation:	21 CFR 882.4560
Classification Name:	Orthopedic Stereotaxic Instrument
Regulatory Class:	Class II
Product Code:	OLO
Predicate Device:	VectorVision Fluoro 3D (K070106)

1 INTENDED USE:

Spine & Trauma Navigation System is intended as an intraoperative image-guided localization system to enable 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 implant size planning and navigation on rigid bone structures with precalibrated and additional individually-calibrated surgical tools.

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.

2 DEVICE DESCRIPTION:

This device is an image guided surgery system for navigated treatments in the fields of spine and trauma surgery, whereas the user may use 3D image data based on CT, MR or XT. The Software supports the surgeon in clinical procedures by displaying tracked instruments in patient image data.

Operator profile

The operator's profile for this devices are Neuro / Ortho / Spine / Trauma surgeons or their assistants having a 3D image acquisition system (such as CT or 3D C-arm) in combination with a Brainlab navigation system.

Patient population

The patient population includes 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).

Intended use environment

The application shall be used in an operating room / suite.

Operating principle

Infrared passive marker based tracking as provided by the optical tracking camera unit of the navigation station is used to determine the instrument's and patient's position. The relation between the patient and the reference attached to the patient is realized with a registration (manually or automatic).

Primary operating functions

Primary Operating Function	Frequently used function	Safety related function
Set up system, start software	✓	
Loading of already (automatically or manually) registered pre-/ intra-operatively acquired CT or Fluoro3D data	✓	✓
Registration of intra-operatively acquired Fluoro 3D data	✓	✓
Navigate on fused pre- / or intra-operatively acquired 3D spinal data (CT/ XT fused to MR/ XT/ CT/ PET)		✓
Navigating CT/ XT and fused MR/XT/ CT/PET data with pre-planned content (objects, screws, etc.)		✓
General navigation in 3D datasets	✓	✓
Navigation of manually calibrated instruments	✓	✓
Navigation of pre-calibrated instruments	✓	✓
Verification of registration accuracy	✓	✓
Verification of instrument accuracy	✓	✓
Store data, shut down system, store system	✓	

Use scenarios

The system is placed in a way that the surgeon can easily watch the screen(s) and interact with the system during the procedure, but sterility is not compromised. The camera is positioned in a way that it has an unobstructed view on the surgical field.

The patient is positioned and draped in the usual manner, taking into account that the reference geometry has to be attached to the relevant anatomical structure in a way that it is not disturbing the latter workflow. The surgical approach is performed. A reference array is attached to the relevant bony structure using conventional surgical techniques (either under sight or minimally invasive). The 3D dataset is either acquired or loaded and subsequently registered.

After the scan has been transmitted to the navigation system or the registration computation has been performed, the surgeon is asked to verify the success of the registration with a general instrument or a dedicated pointer.

After successful verification the surgeon is able to access pre-planned objects, to plan or re-plan screws / trajectories and to visualize manually or pre-calibrated surgical instruments.

Intended part of the body or type of tissue applied to or interacted with

This system has different components, whereas most of them are software. Therefore, only instruments may get in contact with a patient, some instruments are included to perform the surgery. All Instruments are used temporarily for orientation within the situs or for preparations to be able to implant 3rd party devices, which are not part of this system.

Such instruments can be used at rigid bony structures, such as a long bone or vertebra, where the user wants to use this navigation software according to the indications for use.

3 SUBSTANTIAL EQUIVALENCE

The Spine & Trauma Navigation System has similar functionality, intended use, technological characteristics, and typical users as the predicate device.

The proposed software modification was performed to correct a display issue within the Spine & Trauma Navigation System software that can occur when a user changes navigation workflows. The issue was caused by an erroneous orientation of the anatomical slices that were displayed together with a projected instrument representation within axial and coronal/sagittal views of the image data, while the instrument tip was permanently correctly displayed.

The proposed software modification required a local software code change consisting of 14 lines of code and is restricted to two source files.

Since the programming structure for the current display logic was already intended in the detailed design, the software correction did not require any change to the existing software architecture or to the unit tests.

There was no change of intended use, technological characteristics or typical users.

4 VERIFICATION/VALIDATION SUMMARY

Performance Testing

The following verification methods were successfully applied:

- Interactive tests according to verification documents related to changed software parts (software code change verification)
- Interactive tests according to verification documents related to unchanged software parts (regression tests)
- Code review of the software change
- Software memory leakage tests using VLD (Visual Leak Detector)
- Static code analysis (Lint) for changed software parts

Worst case scenarios were considered. New verification activities were performed after extension of existing test cases. They cover switching between different applications within one navigation session and now additionally comprise the missing test scenario for the display issue which caused the software modification request. In order to prevent software changes to have impact on non-changed design parts, regression tests were included to the test protocols.

Design verification testing that was performed to support modifications to the Spine & Trauma Navigation System software met all design and performance requirements.

5 CONCLUSION

The modified device is substantially equivalent to the currently marketed Spine & Trauma Navigation System based upon design verification test results and the indications for use.