August 2, 2023

Brainlab AG
Sadwini Suresh
QM Consultant
Olof-Palme-Str.9
Munich, BY 81829
Germany

Re: K223553
Trade/Device Name: Spine Planning 2.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: June 30, 2023
Received: June 30, 2023

Dear Sadwini Suresh:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223553

Device Name
Spine Planning 2.0

Indications for Use *(Describe)*
Spine Planning is intended for pre- and intraoperative planning of open and minimally invasive spinal procedures. It displays digital patient images (CT, Cone Beam CT, MR, X-ray) 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.

BRAINLAB

K223553
510(k) Summary

June 30, 2023

General Information	
Manufacturer	Brainlab AG; Olof-Palme Str.9; 81829, Munich, Germany
Establishment Registration	8043933
Trade Names	Spine Planning 2.0 • Spine Planning • Elements Spine Planning • Elements Planning Spine
Classification Name	Orthopedic Stereotaxic Instrument
Product Code	OLO
Regulation Number	882.4560
Regulatory Class	II
Panel	Orthopedic
Predicate Device	K212245 Spine and Trauma Navigation System, Spine & Trauma 3D Navigation, Instrument Selection, Fluoro 3D, Registration Software Fluoro 3D, Registration Software Paired Point, Registration Software Spine Surface Matching, Spine Planning, Elements Screw Planning Spine, Elements Spine Screw Planning
Contact Information	
Primary Contact	Sadwini Suresh QM Consultant Regulatory Affairs Phone: +49 89 99 15 68 0 Email: regulatory.affairs@brainlab.com
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1 INDICATIONS FOR USE

Spine Planning is intended for pre- and intraoperative planning of open and minimally invasive spinal procedures. It displays digital patient images (CT, Cone Beam CT, MR, X-ray) and allows measurement and planning of spinal implants like screws and rods.

2 DEVICE DESCRIPTION

The Spine Planning software allows the user to plan spinal surgery pre-operatively or intra-operatively. The software is able to display 2D X-Ray images and 3D datasets (e.g. CT or MR scans). The software consists of features for automated labelling of vertebrae and proposals for screw and rod implants, proposals for measurement of spinal parameters.

The device can be used in combination with spinal navigation software during surgery, where pre-planned or intra-operatively created information can be displayed, or solely as a pre-operative tool to prepare the surgery.

AI/ML algorithms are used in Spine Planning for

- Detection of landmarks on 2D images for vertebrae labeling and measurement and
- Vertebra detection on Digitally Reconstructed Radiograph (DRR) images of 3D datasets for atlas registration (labeling of the vertebra).

The AI/ML algorithm is a Convolutional Neuronal Network (CNN) developed using a Supervised Learning approach. The algorithm was developed using a controlled internal process that defines activities from the inspection of input data to the training and verification of the algorithm.

3 SUBSTANTIAL EQUIVALENCE

The Subject Device has similar intended use and technological features as the predicate devices. An overview of the similarities and differences can be found in the tables below:

Device	Name
Subject Device	Spine Planning 2.0
Predicate device (K212245)	Spine Planning 1.0

Topic/ Feature	Predicate Device (Spine Planning 1.0 (K212245))	Subject Device (Spine Planning 2.0)	Comment
Indications for use	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.	Spine Planning is intended for pre- and intraoperative planning of open and minimally invasive spinal procedures. It displays digital patient images (CT, Cone Beam CT, MR, X-ray) and allows measurement and	No change in the indications. Image modalities that are supported have been included.

		planning of spinal implants like screws and rods.	
Intended use environment	The planning part of the use case shall be done in an office or in the operating room.	The device can be used in an office / team room or in the operating room.	Identical
Supported Imaging Modalities	- Computed tomography (CT)	- CT - Magnetic resonance (MR) - Cone Beam CT (XT) - X-ray	Additional modalities effect measurement or screw planning features
Vertebra Labeling	Automatic detection of thoracic and lumbar vertebrae. User approval of calculated automatic labeling. No functionality to change the calculated labeling.	Automatic detection of cervical, thoracic, lumbar, and sacral vertebrae. Ability to adjust automatic labeling for correction if needed. Automatic labeling can be discarded and performed manually. User approval of labeling.	New features: - Addition of cervical and sacral spinal regions in subject device. - Ability to adjust and correct labeling. - Possible to do performed manual labeling. Functionality tested during verification testing.
Anatomical Variations	N/A	Adjustment of anatomical chain to account for anatomic variations. Depending on patient anatomy, it is possible to exclude T12 and/or L5 and include T13 and/or L6. To be added manually by user.	New feature.
Spinal Parameter Proposals	N/A	Able to add spinal parameters on X-rays based on AI/ML generated landmarks. To be manually reviewed and approved.	New feature.

		Where AI/ML landmarks are unavailable all spinal parameters can be added manually, reviewed, and approved.	
Manual Measurements	N/A	Manual placement and adjustment of angles and open angles on X-rays.	New feature.
Automatic Screw Proposals	Automatic screw proposals provided for thoracic and lumbar pedicle screws.	Automatic screw proposals provided for cervical (lateral mass or pedicle), thoracic (pedicle), lumbar (pedicle), sacral (pedicle and alar iliac), and iliac regions.	Similar function to predicate. New screw proposal algorithm with additional functionality used in subject device.
Screw Planning	Adjustment of screw length, diameter, and position. Creation of manual screws. Addition of automatic screw proposals. User approval of all screws required.	Adjustment of screw length, diameter, and position. Creation of manual screws. Addition of automatic screw proposals. Change of screw type (cervical and sacral regions only) User approval of all screws required.	Adjustment of screws, creation of manual screws and screw approval is similar to predicate. New features. Possible to change type of screw between lateral mass and pedicle screw types (cervical region) or pedicle and alar iliac screw types (Sacral region).

4 PERFORMANCE DATA

Software Verification:

Software verification was performed, verifying the software requirements through integration tests, and unit tests. Incremental test strategies have been set up after verification of the first release candidate for changes with limited scope. In this case, an impact analysis of the modifications is performed and tests to be performed are identified and planned correspondingly. That means, not all tests have to be performed but only a subset, as some of the previous tests are not affected by the change and remain therefore valid.

Software verification verifies all specifications, including SOUP items and cybersecurity.

For newly added components, integration tests were carried out, in addition to the individual component verification.

AI/ML Detected X-Ray Landmarks Assessment:

This test was conducted to assess the AI/ML detected landmarks on X-rays which are used by the software for automatic measurement proposals. This was done by quantifying the object detection, quality of vertebra level assignment, the quality of landmark predictions, and the performance of the observer view direction for 2D X-rays from the Universal Atlas Transfer Performer 6.0.

Screw Proposal Algorithm Evaluation:

The purpose of this testing was to compare the newly proposed screw proposal algorithm to the predicate and back-up algorithms. Thoracic and lumbar pedicle screw proposals generated by the new algorithm were found to be similar to thoracic and lumbar pedicle screw proposals generated by the predicate algorithm.

Usability Evaluation:

Summative usability testing was planned and performed in order to validate that the Spine Planning 2.0 can be used by the intended user group. The summative usability testing identified no critical use related problems.

5 CONCLUSION

The performed verification and validation activities established that the set requirements were met and that the device performs as intended.

The Subject Devices' comparison with the Predicate Device establishes that they have similar functionality, intended use and technological characteristics. Therefore, we consider that the Subject Device can be considered substantially equivalent to the predicate device.