April 19, 2022

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

Re: K213930
Trade/Device Name: Brainlab Elements Guide XT, Guide 3.0
Regulation Number: 21 CFR 882.5855
Regulation Name: Brain Stimulation Programming Planning Software
Regulatory Class: Class II
Product Code: QQC
Dated: February 24, 2022
Received: February 28, 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,

CDR Jitendra Virani
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K213930

Device Name
Brainlab Elements Guide XT, Guide 3.0

Indications for Use *(Describe)*
Brainlab Elements Guide XT provides functionality to assist medical professionals in planning the programming of stimulation for patients receiving approved Boston Scientific deep brain stimulation (DBS) devices.

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 K213930

April 18, 2022

General Information	
Manufacturer	Brainlab AG; Olof-Palme Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Device Name	Brain stimulation programming planning software
Trade Name	Brainlab Elements Guide XT; Guide (3.0)
Classification Name	Brain stimulation programming planning software
Product Code	QQC
Regulation Number	882.5855
Regulatory Class	II
Panel	Neurology
Predicate Devices	Predicate device: SureTune4 Software (DEN210003)

Contact Information	
Primary Contact	**Alternate Contact**
Chiara Cunico Manager RA Phone: +49 89 99 15 68 0 Email: chiara.cunico@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. Indications for Use

Brainlab Elements Guide XT provides functionality to assist medical professionals in planning the programming of stimulation for patients receiving approved Boston Scientific deep brain stimulation (DBS) devices.

2. Device Description

Brainlab Elements Guide XT is a software application designed to support neurosurgeons and neurologists in Deep Brain Stimulation (DBS) treatments. It enables stimulation field simulation and visualization of the stimulation field model in the context of anatomical images. This functionality can be used to aid in lead parameter adjustment.
Brainlab Elements Guide XT is used in combination with other applications that provide functionality for image fusion, segmentation, etc.

Guide XT is compatible with selected Boston Scientific leads and implantable pulse generators but does not directly interact with the surgeon.

The subject device Brainlab Elements Guide XT consists of multiple software components including the Guide XT 3.0 application that provides the core functionality for stimulation field model creation and visualization in the context of the patient anatomy. Below the full list of components:

Name	Description
Content Manager 2.7	This software provides a start screen. The different applications and available video sources are visualized and can be selected.
Backbone 1.6	The software receives and distributes live-video streams, video routing information and other general messages from/to applications on the local computer.
Backbone Viewer 1.6	The software displays images that were distributed by Backbone and capturing display including user input content of connected displays to send it to the Backbone
Patient Selection 6.1	The software allows to manage patients' records available in different sources configured in the system. Additionally, Patient Selection application allows managing patients in the sense of editing, merging, deleting and creation as part of the general IT-infrastructure and converting and exporting planning contents into other data formats.
Data Selection 6.1	The software main purpose is to search, filter and select data. This data is sorted into clusters and made available to the user.
Dicom Proxy 4.3	Allows to retrieve patient data from hospital servers and distribute it to other software applications. It is used as central patient data server for patient data communication, storage and exchange based on the DICOM standard. This is an externally facing electronic interfaces via USB and LAN.
Brainlab Elements Trajectory Planning 2.5	Software for trajectory planning and lead definition. Uses the lead localization configuration of the Trajectory Planning 2.5. Lead Localization (Element) allows the creation of trajectories and automatic detection of leads in post-operative images.
Guide XT 3.0	This software enables stimulation field simulation and visualization of the stimulation field model in the context of anatomical images.

Brainlab Element Guide XT is compatible with the following selected Boston Scientific leads and implantable pulse generators.

Device	Article No.
DBS Lead	DB-2201
Vercise™ Cartesia™ 8 Contact DBS Directional Lead	DB-2202
Vercise Gevia™ 16 Contact Implantable Pulse Generator	DB-1200
Vercise™ Implantable Pulse Generator	DB-1110
Vercise PC™ Implantable Pulse Generator	DB-1140
Vercise Genus™ P16 Implantable Pulse Generator	DB-1416
Vercise Genus™ P32 Implantable Pulse Generator	DB-1432
Vercise Genus™ R16 Implantable Pulse Generator	DB-1216
Vercise Genus™ R32 Implantable Pulse Generator	DB-1232

These are the primary operating functions:

Primary Operating Functions	Risk Related
Load patient imaging data	X
Fuse Image Sets	X
Create supplemental treatment plan content (e.g. segmentations, fiber tracts)	X

Primary Operating Functions	Risk Related
Define lead position	X
Assign lead attributes	X
Model Lead/IPG Setup	X
Create and adapt stimulation simulations	X
Load Stimulation parameters stored by Programming Application	X
Interactive Viewing of stimulation simulations in the context of the imaging and supplemental information	X
Store Simulations	X
Safe treatment plan data	X

3. Substantial Equivalence

The Subject Device and predicate are similar in terms of:

1. User profile, patient population
2. Identified risks (Patient Discomfort due to collateral Stimulation, Patient Discomfort due to inadequate Stimulation)
3. VTA simulation
4. Annotations of observed clinical effects (Predicate device provides interface to annotate observations made during surgery. The subject device provides interface to annotate observations made during programming.)
5. Lead Localization
6. Trajectory/ Path Coordinates
7. Manual Anatomical Segmentation: Subject Device allows manual outline of the shape of anatomical structures
8. Automatic Anatomical Segmentation: Subject Device registers anatomical atlas to patient and automatically segments anatomical structures.
9. AC/PC Coordinate System: Subject Device allows for manual placement of AC/PC coordinates and the midline plane on an image

The Subject Device and predicate differ in terms of:

1. Subject device only simulates stimulation fields for Boston Scientific electrodes and the predicate device is intended to be used only with Medtronic electrodes.

4. Performance Data

In addition to the software verification testing, usability evaluation was carried out for the Subject Device and the previous version of the Subject Device v 2.0. The data gathered from the version is considered to be representative of the Subject Device as well.
Additionally, the performance test for the VTA (Volume of Tissue Activated) simulation was conducted supporting the use of a proprietary heuristic methodology for the prediction of threshold current (Ith) maps in the vicinity of implanted leads stimulated by the Deep Brain Stimulation (DBS) system from Boston Scientific Neuromodulation (BSN).
The Subject Device was not used for any clinical tests for the purposes of this 510k) submission. Clinical data was leveraged from the existing literature sources to validate the indications and intended use of the device.

5. Conclusion

From the verification and non-clinical tests conducted, the device was demonstrated to be as safe and effective as the predicate device.