April 27, 2023

Brainlab AG
Esther Moreno Garcia
QM Consultant
Olof-Palme-Str. 9
Munich, 81829
Germany

Re: K223734
Trade/Device Name: Ent Em
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: March 28, 2023
Received: March 28, 2023

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 (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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
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Respiratory, ENT and Dental Devices
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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)*
K223734

Device Name
ENT EM

Indications for Use *(Describe)*
ENT EM is intended as an image-guided planning and navigation system to enable ENT procedures. The device is indicated for any medical condition in which a reference to a rigid anatomical structure can be identified relative to images (CT, CTA, X-Ray, MR, MRA and ultrasound) of the anatomy, such as:

- Intranasal structures and Paranasal Sinus Surgery
  - o Functional endoscopic sinus surgery (FESS)
  - o Intranasal structures and paranasal sinus surgery, including revision and distorted anatomy
- Anterior skull base procedures

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

April 27, 2023

General Information	
Manufacturer	Brainlab AG; Olof-Palme-Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Trade Name	ENT EM
Classification Name	Ear, nose, and throat stereotaxic instrument
Product Code	PGW
Regulation Number	882.4560
Regulatory Class	Class II
Panel	Neurology - Ear Nose & Throat
Predicate Device(s)	K200723 StealthStation FlexENT, StealthStation S8 ENT Software 1.3
Reference Device(s)	K213989 Cranial EM System

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

ENT EM is intended as an image-guided planning and navigation system to enable ENT procedures.

The device is indicated for any medical condition in which a reference to a rigid anatomical structure can be identified relative to images (CT, CTA, X-Ray, MR, MRA and ultrasound) of the anatomy, such as:

- Intranasal structures and Paranasal Sinus Surgery
  - Functional endoscopic sinus surgery (FESS)
  - Intranasal structures and paranasal sinus surgery, including revision and distorted anatomy
- Anterior skull base procedures

2. Device Description

The Subject Device **ENT EM** is an image guided planning and navigation system to enable navigated surgery during ENT procedures. It offers guidance for setting up the EM equipment, different patient image registration methods and instrument selection and calibration to allow surgical navigation by using electromagnetic tracking (EM) technology. The device provides different workflows guiding the user through preoperative and intraoperative steps.

To fulfill this purpose, it links patient anatomy (using a patient reference) and instruments in the real world or “patient space” to patient scan data or “image space”. This allows for the continuous localization of medical instruments and patient anatomy for medical interventions in ENT procedures.

The software is installed on a mobile Image Guided Surgery (IGS) platform (Kick 2 Navigation Station or Curve Navigation 17700) to support the surgeon in clinical procedures by displaying tracked instruments in patient’s image data. The IGS platforms consist of a mobile Monitor Cart and an EM tracking unit for image guided surgery purposes.

ENT EM consists of: Several software modules for registration, instrument handling, navigation and infrastructure tasks, IGS platforms and surgical instruments for navigation, patient referencing and registration.

With this submission, an already existing feature is now performed introducing a new algorithm using artificial intelligence and machine learning (AI/ML). This ML based functionality is used as an aid in the registration step (in surface matching) by allowing a pre-registration based on guide points. These guide points or landmarks are delivered by a ML based calculation. 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. The training process begins with the model observing, learning, and optimizing its parameters based on the training pool data. The model's prediction and performance are then evaluated against the test pool. The test pool data is set aside at the beginning of the project. This is a static algorithm (locked).

3. Substantial Equivalence

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICE

Characteristic	Predicate Device K200723	Reference Device K213989	Subject device ENT EM
Indications for use	The StealthStation FlexENT™ system with the StealthStation™ ENT software, is intended as an aid for precisely locating anatomical structures in	Cranial EM is intended as an image-guided planning and navigation system to enable neurosurgery procedures. The device is indicated for any medical condition in	All devices are intended for the localization of anatomical structures (navigation). Compared to predicate device, same indications for use (Sinus

	either open or percutaneous ENT procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to images of the anatomy. This can include, but is not limited to, the following procedures: - Functional Endoscopic Sinus Surgery (FESS) - Endoscopic Skull Base procedures - Lateral Skull Base procedures	which a reference to a rigid anatomical structure can be identified relative to images (CT, CTA, X-Ray, MR, MRA and ultrasound) of the anatomy, such as: • Cranial Resection -Resection of tumors and other lesions -Resection of skull-base tumor or other lesions •Intracranial catheter placement	surgery and anterior skull base procedures).
Localization technique	Electromagnetic tracking: The Side Emitter emits low intensity and varying electromagnetic field which induce small currents in the sensors embedded EM instruments. The position and spatial orientation of the sensors integrated in the EM instruments are calculated in the Instrument Interface Box.	Electromagnetic tracking: The Field generator emits low intensity and varying electromagnetic field which induce small currents in the sensors embedded in the EM instruments. The position and spatial orientation of the sensors integrated in the EM instruments are calculated in the Base station.	Same localization technique compared to both predicate and reference device. The EM tracking device used is the same as in the reference device.
System accuracy	Under representative worst-case configuration, the StealthStation FlexENTt and S8 Systems With StealthStation S8 ENT vl.3 Software, has demonstrated performance in 3D positional accuracy with a mean error <= 2.0 mm and in trajectory angle accuracy with a mean error <= 2.0 degrees.	Under representative worst case configuration, the Cranial EM System is tested to ensure that its mean location error is ≤ 2 mm and its mean trajectory angle error is ≤ 2 degrees.	Under representative worst case configuration the subject device achieves the same system accuracy performance (mean location error is ≤ 2 mm and its mean trajectory angle error is ≤ 2 degrees) as both predicate and reference device.
Programming language	C++	C++	Same programming language compared to both predicate and reference device.

Registration methods	Exam-to-Exam Registration Features: Identify Merge Registration Manual Merge Registration Automatic Merge Registration Patient registration Features: PointMerge registration Tracer registration Touch registration	Landmark registration Surface matching registration	Registration methods are similar compared to the predicate device and same as reference device.
Detection of anatomical landmarks/guide points	N/A	Detection of anatomical landmarks used for a pre-registration step within the Surface matching registration based on an atlas of the human anatomy.	Compared to the reference device, overall functionality is the same, but landmarks are delivered by an AI/ML based method. Testing showed equivalent performance with and without AI/ML.
Navigation features	Navigation of precalibrated and non-precalibrated instruments on different views enriched with additional planning content.	Navigation of precalibrated and non-precalibrated instruments on different views enriched with additional planning content.	Same navigation concept as both predicate and reference device.
IGS Platforms	IGS platforms consisting of mobile monitor cart and an EM tracking unit: • StealthStation FlexENT	IGS platforms consisting of mobile monitor cart and an EM tracking unit: • Curve Navigation 17700 (17700) • Kick 2 Navigation Station EM (18202)	Similar to primary predicate and same IGS platforms compared to reference device (with minor modifications to e.g. strengthen cybersecurity)
Instruments	N/A	Instruments for patient referencing, registration and navigation. Compatible 3rd party instruments from KLS Martin.	Same instruments as refence device. Former KLS Martin Instruments are now legally manufactured by Brainlab.

4. Performance Data

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

Software Verification and Validation Testing

To address differences in terms of software development and the specific implementation of features, 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." This included product specifications, risk analysis and software verification and validation testing. The software (ENT EM 1.2) for this device was considered as a "major" level of concern.

In particular, ENT EM implements a feature for landmark detection in the registration software using AI/ML. The same feature without AI/ML was already used in the reference device. Performance testing comparing conventional to machine learning based landmark detection were performed showing equivalent performance as in the reference device.

System accuracy testing

The positional and angular navigation accuracy for ENT procedures of the Subject Device including the software, the platforms and the instruments was evaluated considering a realistic clinical setup and representative worst case scenarios. The results show the following acceptance criteria are fulfilled:

- Mean Positional Error of the placed instrument's tip ≤ 2 mm
- Mean Angular Error of the placed instrument's axis ≤ 2°

Therefore, the Subject Device achieves the same accuracy performance as both predicate and reference device.

Usability

To account for differences regarding the intended user group compared to the reference device and the different workflow steps and GUI implementation compared to the predicate device a summative usability evaluation in a simulated clinical environment was carried out, where the user had to go through all main steps and frequently used functions. This showed ENT EM is safe and effective for use by the intended user group.

Electrical safety and electromagnetic compatibility (EMC)

Compliance to electrical safety, RFID and EMC was evaluated on the Subject device according to the standards: IEC 60601-1, AIM 7351731 and IEC 60601-1-2. The tests have shown that the subject device performs as intended.

Instruments

Due to the change in legal manufacturer of the skull reference instruments, the biocompatibility testing and reprocessing validation for the instruments was provided in order to demonstrate their biological safety and appropriateness of the cleaning, disinfection and sterilization methods. This included:

- Biocompatibility assessment considering different end points
- Cleaning and disinfection evaluation/reprocessing validation

The mechanical properties of instruments were also evaluated considering the typical torsional strengths, torques and conditions the instruments can be subject to during their use.

No clinical testing was needed for the Subject Device since the EM tracking technology in the scope of image guided surgery for the included indications for use is well established in the market. Bench testing demonstrated that the device performs as the predicate and that no different questions on safety or effectiveness were raised.

5. Conclusion

The comparison of the Subject Device with the predicate and reference device shows that ENT EM has similar functionality, intended use and technological characteristics as the predicate and reference devices. Based on this comparison and the performance testing conducted, the Subject Device is considered substantially equivalent to the predicate device.