September 8, 2022

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

Re: K213989
Trade/Device Name: Cranial EM System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: August 9, 2022
Received: August 9, 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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic 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)*
K213989

Device Name
Cranial EM System

Indications for Use *(Describe)*
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 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
  - o Resection of tumors and other lesions
  - o Resection of skull-base tumor or other lesions
- Intracranial catheter placement

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

September 8, 2022

General Information	
Manufacturer	Brainlab AG; Olof-Palme Str.9; 81829, Munich, Germany
Establishment Registration	8043933
Device Name	Neurological Stereotaxic Instrument
Trade Name	• Cranial EM system
Product Code	HAW
Regulation Number	882.4560
Regulatory Class	II
Panel	Neurology
Predicate Devices	**Primary:** StealthStation Cranial Software v1.3.0 (K201175) by Medtronic **Secondary:** Kolibri Cranial Magnetic (K042391) by Brainlab AG **Reference Device:** Cranial IGS System (K192703) by Brainlab AG

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

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 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

2. Device Description

The Subject Device, Cranial EM System, consists of software and hardware components. 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 cranial procedures. The tracking data are acquired via electromagnetic tracking.

Cranial EM is a touchscreen-based intraoperative navigation software. The placement of surgical instruments in a three-dimensional representation overlaid on anatomical image sets, such as MR and/or CT, can support the surgeon during various surgical interventions.
Cranial EM uses scanned images of the patient that are acquired before surgery is performed.

The following software make up the main module of the device:

1. EM Setup 2.1
2. Head Registration 2.1
3. EM Instruments 2.1
4. Navigation 2.1

The Subject Device Consists of the following hardware components:

Platforms:

1. Kick 2 Navigation Station (Article Number: 18202)
2. Curve Navigation 17700 (Article Number: 17700)

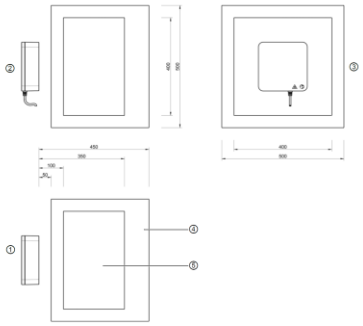
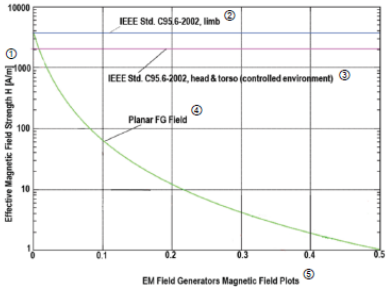
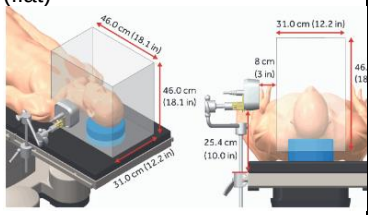
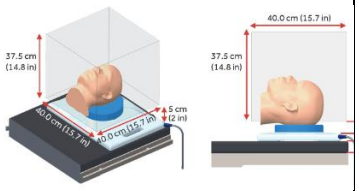
Instruments:

1. EM Patient Reference 2.0 (18099-24)
2. EM Pointer (18099-02C)
3. EM Instrument Reference (18099-05A)
4. EM Registration Pointer (18099-23)
5. EM Stylet 2.0 (18097-01)
6. EM Short Pointer (18099-27)
7. EM Skull Reference Base (18099-06)

3. Substantial Equivalence

Topic	Subject Device: Cranial EM System	Primary Predicate: StealthStation Cranial Software v1.3.0 (K201175)	Secondary Predicate: Kolibri Cranial Magnetic (K042391)	Reference Device: Cranial Image Guided Surgery System (K192703)	Comment
Indications for Use	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 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 o Resection of tumors and other lesions o Resection of skull-base tumor or other lesions • Intracranial catheter placement	The StealthStation™ System, with StealthStation™ Cranial Software, is intended as an aid for locating anatomical structures in either open or percutaneous neurosurgical 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 cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures): • Tumor resections • General ventricular catheter placement • Pediatric ventricular catheter placement • Depth electrode, lead, and probe placement • Cranial biopsies	The BrainLAB Kolibri IGS System is intended to be an intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a magnetic sensor system or a passive marker sensor system to a virtual computer image space on a patient's preoperative diagnostic image data set being processed by the Kolibri computer workstation. 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, a long bone, or vertebra, can be identified relative to a CT, X-ray or MR based model of the anatomy. Example image guided cranial surgery procedures include but are not limited to: 1. Tumor resections 2. Skull base surgery 3. Cranial biopsies 4. Craniotomies/Craniectomies 5. Pediatric Catheter Shunt Placement 6. General Catheter Shunt Placement	The Cranial IGS System, when used with a compatible navigation platform and compatible instrument accessories, is intended as an image-guided planning and navigation system to enable navigated surgery. It links instruments to a virtual computer image space on patient image data that is being processed by the navigation platform. The system 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, including: •Cranial Resection o Resection of tumors and other lesions o Resection of skull-base tumor or other lesions •AVM Resection •Cranial biopsies •Intracranial catheter placement •Intranasal structures and Paranasal Sinus Surgery •Functional endoscopic sinus surgery (FESS) •Revision & distorted anatomy surgery all intranasal structures and paranasal sinuses	The wording has been rephrased with the purpose to improve readability and clarity without affecting the content. The included procedures are grouped differently: resections are bundled and approaches as craniotomy not listed separately. Catheter placement are bundle without patient population specifications. Biopsies, depth electrode placement, ENT indications or AVM are not part of the indications of the subject device. The Subject Devices' indications are within the subset of the primary predicate and reference devices' indications.

Topic	Subject Device: Cranial EM System	Primary Predicate: StealthStation Cranial Software v1.3.0 (K201175)	Secondary Predicate: Kolibri Cranial Magnetic (K042391)	Reference Device: Cranial Image Guided Surgery System (K192703)	Comment
Localization technique based on:	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.	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 of the EM instruments. The position and spatial orientation of the sensors integrated in the EM instruments are calculated in the Base station.	Optical Tracking- N/A	General localization techniques remain the same w.r.t. the predicate devices: K201175 and K042391. K19270 uses an optical tracking system. Therefore it´s not comparable with the other systems
Tracking Accuracy	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 StealthStation S8 System with StealthStation Cranial Software v1.3.0, has demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error ≤ 2 degrees.	≤ 2.5 mm distance RMS (Root Mean Square) ≤ 2.5° angle RMS (Root Mean Square)	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.	The subject device and primary predicate device are both meeting the same accuracy requirements. Refer to Ground truth accuracy test report [0000279513]

Topic	Subject Device: Cranial EM System	Primary Predicate: StealthStation Cranial Software v1.3.0 (K201175)	Secondary Predicate: Kolibri Cranial Magnetic (K042391)	Reference Device: Cranial Image Guided Surgery System (K192703)	Comment
Field Generator	Manufacturer: NDI Localizer: Aurora V3 Emitter Type: side Tracking Volume: 500x500x400 mm  Field strength: 	Manufacturer: Medtronic Localizer: AXIEM III Emitter Type: side, flat Tracking Volume: 460x460x310 mm (side), 400x400x375 mm (flat)   Field strength: < 2.10 x (f / 3350) V/m where f is the frequency in Hz from 3kHz to 5MHz as set by IEEE Standard C95.1 - 2005	Manufacturer: NDI Localizer: Aurora V1 Emitter Type: side Tracking Volume: 500x500x500 mm Field strength: same as subject device.	Optical Tracking- N/A	The tracking volume of the subject device and predicate devices covers the region of interest. The subject device has a slightly bigger volume in x, y and z direction compared to the primary predicate. Compared to the secondary predicate, the volume of the field generator was reduced in the new version to 400 mm in z direction to ensure accurate positioning of the head in the tracking volume. During Usability testing it was verified that representative clinical users are able to position, register and navigate within the reduced/new tracking volume of the subject device [Usability summary 0000269739, rev. 1].

Topic	Subject Device: Cranial EM System	Primary Predicate: StealthStation Cranial Software v1.3.0 (K201175)	Secondary Predicate: Kolibri Cranial Magnetic (K042391)	Reference Device: Cranial Image Guided Surgery System (K192703)	Comment
Touch screen	Curve Navigation 17700: Type: LCD TFT display Size: 31.5” Color depth: 1.073B colors Resolution: 3840 x 2160 pixels Touch technology: Projected capacitive Kick 2 Navigation Station 18202: Type: LCD TFT display Size: 21.5” Color depth: 16.7M colors Resolution: 1920 x 1080 pixels Touch technology: Projected capacitive	Monitor dimension: 15.3” x 25.5” x 2.5” Resolution: 2560x1440 pixels	Type: LCD TFT display Size: 15” Color depth: 16M colors Resolution: 1024 x 768 pixels Touch technology: AccuTouch resistive	-----	Two new platforms as hardware components have been included with the Subject Device.
Electrical specifications	Curve Navigation 17700: • Frequency: 50 / 60 Hz • Power consumption: 7.6 A @ 100 VAC, 3.3 A @ 240 VAC Kick 2 Navigation Station 18202: • Frequency: 50 / 60 Hz Power consumption: 3 A @ 100 VAC, 1.5 A @ 240 VAC	Frequency: 50 / 60 Hz Input voltage: 100 – 230 V Maximum power: 900 VA Typical power dissipation: 400 – 600 VA	Frequency: 50 / 60 Hz Power consumption: 3 A @ 100-115 V, 15 A @ 230 V	-----	Two new platforms as hardware components have been included with the Subject Device
Data loading possibilities	• USB • Network Wireless transfer	• USB • CD / DVD Wireless transfer	• USB CD/DVD	• USB • Network Wireless transfer	Only state of the art data loading possibilities are supported. Cybersecurity summary [0000271450] contains the details on risks related to cybersecurity and the measures implemented included additional recommended considerations.

Topic	Subject Device: Cranial EM System	Primary Predicate: StealthStation Cranial Software v1.3.0 (K201175)	Secondary Predicate: Kolibri Cranial Magnetic (K042391)	Reference Device: Cranial Image Guided Surgery System (K192703)	Comment
Imaging modality supported [Head Registration application]	CT, MR	X-Ray based, MR based, Nuclear Medicine based	CT, MR	CT, MR	CT and MR are the main supported modalities where patient registration is also supported. Nuclear medicine based modalities are supported for display in the navigation. Main supported modalities are same.
Planning features [Navigation App]	• Plan Entry and Target Selection • 3D Model Building	• Plan Entry and Target Selection • 3D Model Building • Advanced Visualization • Create Patient Based Anatomical Coordinate Space Stereotactic • Frame Settings Brain Atlas: Schaltenbrand-Wahren Atlas with Talairach Grid STarFix™ Designer Annotations	N/A	• Plan Entry and Target Selection • 3D Model Building • Advanced Visualization	Planning features relevant for the covered indications for use are same.

Topic	Subject Device: Cranial EM System	Primary Predicate: StealthStation Cranial Software v1.3.0 (K201175)	Secondary Predicate: Kolibri Cranial Magnetic (K042391)	Reference Device: Cranial Image Guided Surgery System (K192703)	Comment
Navigation Views [Navigation App]	• Axial • Coronal • Sagittal • Inline 1 • Inline 2 • Probe's Eye • 3D Overview • Video View (e.g: Endoscope) Autopilot-View	• Axial • Coronal • Sagittal • Trajectory 1 • Trajectory 2 • Probes Eye • Target Guidance, Trajectory Guidance • Endoscopic • Look Ahead • Ultrasound Video In • Ultrasound Overlay, 3D, • Microscope Injection, Video Input	• Axial • Coronal • Sagittal • Probes Eye	• Axial • Coronal • Sagittal • Inline 1 • Inline 2 • Probe's Eye • Split Probe's Eye • Skin Overview • Skin Probe's Eye • Bone Overview • 3D Overview • Video View • Ultrasound video • Acquired 2-D ultrasound images • Acquired 3-D ultrasound data sets • Ultrasound reconstruction: superimposition of ultrasound video with the correlated diagnostic image data • Autopilot-View	Main navigation views are identical to those in primary and secondary predicate devices.

4. Performance Data

The following tests were conducted:

- System accuracy tests (Software + platforms + instruments)
- Platform expected service life verification
- Biocompatibility and reprocessing and shelf life sterility tests for applicable instruments
- User contact biocompatibility assessment
- Routine Software verification
- Platform Verification
- Usability Evaluation

No clinical testing submitted for the Subject Device. Data from existing literature was leveraged for validating the Subject Device's indications.

5. Conclusion

Based on the battery of non-clinical testing conducted for the Subject Device as listed above, and based on the Substantial Equivalence discussion, the Subject Device was demonstrated to be as safe and effective as the predicate devices for the intended use and indications stated.