October 8, 2020

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

Re: K192703
Trade/Device Name: Cranial Image Guided Surgery System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: September 2, 2020
Received: September 8, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192703

Device Name
Cranial Image Guided Surgery System

Indications for Use *(Describe)*
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
  - Resection of tumors and other lesions
  - 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

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
CRANIAL IMAGE GUIDED SURGERY SYSTEM

IN ACCORDANCE WITH REQUIREMENTS OF 21 CFR PART 807.92

GENERAL INFORMATION	
Manufacturer:	Brainlab AG Olof-Palme-Straße 9 81829 Munich Germany Ph: + 49-899915681 0 Fax: +49 89 991568 5033
Establishment Registration #:	8043933
Date of preparation:	October 8th, 2020
Device Name:	Cranial Image Guided Surgery System
Trade Name(s):	Navigation Software Cranial Navigation Software ENT Registration Software Cranial Automatic Registration 2.0 Ultrasound Navigation Software (BK) Intraoperative Structure Update
Classification Name:	Neurological Stereotaxic Instrument, 21 CFR 882.4560
Classification Product Code	HAW
Review Panel:	Neurology
Device Class:	Class II
Primary Predicate Device:	K092467, Cranial Image Guided Surgery System, by Brainlab AG
Secondary Predicate Device:	K070106, VectorVision Fluoro 3D, by Brainlab AG

CONTACT INFORMATION	
Primary contact person	**Alternative contact person**
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INTENDED USE / INDICATIONS FOR USE

Cranial IGS System:

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
  - Resection of tumors and other lesions
  - 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

DEVICE DESCRIPTION

The **Cranial IGS System** consists of software and hardware (instruments) components that when used with a compatible navigation workstation or “IGS platform” enables navigated surgery. It links 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 and ENT procedures.

OPERATOR PROFILE

The application is intended to be used by medical professionals who perform neurosurgery and ENT surgery (e.g. neurosurgeons, surgeons’ assistants and operating room personnel).

PATIENT POPULATION

There are no demographic, regional or cultural limitations for patients.

INTENDED USE ENVIRONMENT

The system is developed to run on Brainlab IGS Platform, which shall be used in hospital environments, specifically in rooms which are appropriate for surgical interventions (e.g. operation rooms).

OPERATING PRINCIPLE
The operating principle of the subject device is the following: - Infrared tracking: An infrared camera recognizes an infrared passive marker array which is in a fix position to the patient's head. Suitable instruments can be spatially tracked with respect to this marker array. Alignment of the patient's anatomy to the digital patient image data is performed through localizing surface skin points or landmarks points to the patient (this step is also known as registration). In addition for automatic registration methods, the alignment of the patient's anatomy to the digital patient image data is performed through coordinate transformations of localizing markers. This enables representing the position of a tracked instrument in relation to the patient's anatomy in digital patient image data (this step is also known as navigation). The Subject device interfaces with other Brainlab applications which provides, e.g. planning data.
INTENDED PART OF THE BODY OR TYPE OF TISSUE APPLIED TO OR INTERACTED WITH
The intended part of body depends on the instrument used. Whereas the navigation software does not have any patient contact, some instruments are designed to be used in a sterile environment and also for getting in contact with the patient's bone or soft tissue.
REASON FOR 510(K) SUBMISSION
Additional indication and other changes that do not affect the fundamental scientific technology of the device.
SUBSTANTIAL EQUIVALENCE
The functionality of the subject device has been previously included in the Predicate Devices. The Subject Device specifically takes over the functionalities from the primary predicate device and moved them to separate applications to have dedicated applications for specific tasks. It takes over the ability to navigate on 2D fluoroscopic images, specially, Digital Subtraction Angiographies for arteriovenous malformation resection.

Technological Characteristics of the Subject Device in comparison to the primary predicate device

	Cleared device feature/specifications **Cranial Image Guided Surgery System** (K092467)	Modified device feature/specifications **Cranial Image Guided Surgery System**
Intended Use / Indications for Use	The Cranial IGS System is intended to be an intra-operative 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 patient image data being processed by the navigation 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, CTA, X-Ray, MR, MRA and ultrasound based model of the anatomy. Example procedures include but are not limited to: Cranial Procedures: Tumor resections Skull base surgery Cranial biopsies Craniotomies/ Craniectomies Pediatric Catheter Shunt Placement General Catheter Shunt Placement Thalamotomies/ Palliodotomies ENT Procedures Transphenoidal procedures Maximillary antrostomies Ethmoidectomies Spheno-idotomies/ sphenoid explorations Turbinate resections Frontal sinusotomies Intranasal procedures	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 • Resection of tumors and other lesions • 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 on all intranasal structures and paranasal sinuses
Brainlab IGS Platform	Brainlab Kolibri Brainlab Vector Vision	Brainlab Kick Brainlab Curve

		Brainlab Buzz IGS
Operating Systems	Windows XP	Windows 7 Windows 8.1 Windows 10
Data Inputs	Equivalent	
Tracking Technology	Equivalent	
Navigation Features	Equivalent	
Angio Navigation Views	Navigation of CTA and MRA	Navigation of 2D DSA images
Pre-calibrated Instrument Tracking	Equivalent	
Calibrated Instrument Tracking	Equivalent	

Technological Characteristics of the Subject Device in comparison to the secondary predicate device

	Cleared device feature/specifications **VectorVision Fluoro 3D** (K070106)	Modified device feature/specifications **Cranial Image Guided Surgery System**
Intended Use / Indications for Use	Brainlab Vector Vision fluoro3D 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. VectorVision fluoro3D 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	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:

	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.	Cranial Resection • Resection of tumors and other lesions • 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 on all intranasal structures l and paranasal sinuses
Brainlab IGS Platform	Brainlab Kolibri Brainlab Vector Vision	Brainlab Kick Brainlab Curve Brainlab Buzz IGS
Operating Systems	Windows XP	Windows 7 Windows 8.1 Windows 10
Angio Navigation Views	Fluoro Navigation: Navigation of medical image data based on exact position display of instrument tip.	Angio Views: Navigation of medical image data based on exact position display of instrument tip.

Verification/Validation summary:

Verification:
Verification has been performed according to the Verification Plan and following internal processes to demonstrate that design specifications are met by the device.
The software changes have been tested in accordance with the Brainlab software development life cycle process. Verification and validation testing activities were performed at the software system, integration, and component levels to show sufficient implementation of the changes as per the specifications. Software testing conducted includes:

- System level software verification
- Accuracy testing
- Integration tests with other Brainlab software applications and IGS platforms
- Component level code verification

Furthermore, in accordance with the design controls process, the following tests were deemed required to evaluate the Cranial IGS System performance across the hardware and electrical components:

- Electrical safety
- Electromagnetic compatibility (EMC)

- Biocompatibility
- Sterilization

All testing was utilized to verify the subject device performance as intended.

Validation:

Validation of the functionalities, including nonclinical performance tests (accuracy tests, see below), has been performed in accordance with the internal processes.
Usability tests have been performed as well to ensure that the device can be used safely and that measures against potential use related risks are effective.

Nonclinical performance testing (Accuracy)
The system has a mean accuracy of 2 mm for location error and 2° for trajectory angle error.

The following table summarizes the performance verification results of the system:

	Mean	**Standard deviation**	**99th percentile**
Location error	**1.3 mm**	**0.5 mm**	**2.2 mm**
Trajectory angle error	**0.73°**	**0.34°**	**1.3°**

CONCLUSION
Functionality and features considered as substantially equivalent have been verified and validated. The Cranial Image Guided Surgery System with its set of functionalities is substantially equivalent to its predicate devices.