September 6, 2019

Brainlab AG
Hugo Morales
Regulatory Affairs Manager
Olof-Palme-Str. 9
81829 Munich
Germany

Re: K190250
Trade/Device Name: Microscope Navigation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: August 7, 2019
Received: August 9, 2019

Dear Hugo Morales:

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,

Matthew Krueger, M.S.E.
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)*
K190250

Device Name
Microscope Navigation

Indications for Use *(Describe)*

The Brainlab Navigation System – Microscope Navigation Software is a software module, that when used with a Brainlab navigation system and compatible instrument accessories, is intended as image guided planning and navigation system to enable open and minimally invasive surgery.
It links an instrument and the view of the surgical field (e.g., video, view through surgical microscope) 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 a reference to a rigid anatomical structure can be identified relative to images (CT, CTA, X-Ray, MR, MRA and ultrasound) of the anatomy.

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
MICROSCOPE NAVIGATION 1.5

IN ACCORDANCE WITH REQUIREMENTS OF 21 CFR PART 807.92

Manufacturer:	Brainlab AG Olof-Palme-Straße 9 81829 Munich Germany
Submitter:	Oliver Fleig
Contact person:	Alexander Schwiersch
Summary date	December 14, 2018
Device	Microscope Navigation
Trade name	Microscope Navigation Software
Common name:	Frameless Stereotaxic Navigation System
Classification name:	Neurological Stereotaxic Instrument (21 CFR 882.4560, Product Code HAW)
Predicate Device:	K172820 Microscope Navigation
Regulatory Class:	Class II
Regulation Number:	882.4560
Intended use:	The Brainlab Navigation System - Microscope Navigation Software is a software module, that when used with a Brainlab navigation system and compatible instrument accessories, is intended as image guided planning and navigation system to enable open and minimally invasive surgery. It links an instrument and the view of the surgical field (e.g. video, view through surgical microscope) 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 a reference to a rigid anatomical structure can be identified relative to images (CT, CTA, X-Ray, MR, MRA and ultrasound) of the anatomy.

Device description:

The Microscope Navigation Software (also referred to as subject device or Microscope App) is a software. It runs on a Brainlab navigation system consisting of a computer, a display and an IR tracking camera (referred to as platform) and a Brainlab Image Guided Surgery software (referred to as IGS software).
The Microscope Navigation encapsulates microscope specific functionality and separates it from the IGS software.
The device interfaces with the IGS software and e.g. utilizes the **registration provided by the IGS software.**

The device assists surgeries where a surgical microscope is used. It provides information based on the field of view through the microscope, the microscope position relative to the patient and the medical imaging data of the patient.
The subject device provides functionality to verify and correct a patient registration.
The Microscope Navigation does not provide its own registration.

Reason for 510(k) submission:	Microscope Navigation Version 1.0 has been cleared under K172820, with K082060 VECTORVISION CRANIAL as predicate device. Compared to its predicate device, Microscope Navigation Version 1.0 provides limited interface implementation and compatibilities of the microscope protocols. These interface implementation and compatibilities have been present in K082060 VECTORVISION CRANIAL and have been re-implemented in Microscope Navigation Version 1.5.

Substantial equivalence:

Microscope Navigation has been verified and validated using non-clinical data according to Brainlab procedures for product design and development. The information provided by Brainlab in this Special 510(k) application supports the claim of substantial equivalence to the predicate device.

Microscope Navigation separates microscope specific functionality in an separate application. Microscope specific views are bundled in this application.

Comparison to the Predicate Device

Motorized movement functionality has been re-implemented in the Subject Device to provide full interface implementation to motorized microscopes. All features have already been present in K082060 VECTORVISION CRANIAL:

- Set focus depth to instrument tip
- Bookmarking
- Align to trajectory
- Follow instrument tip
- Align to instrument axis

Verification summary:

Test	Test Method Summary	Results
Safety Measures	Verification of implemented limits and automatic safety measures for the motorized movements	All tests passed
Motorized movement user interface	Interactive testing of user interface	All tests passed
Communication protocols	Verification of the communication between the subject device and the integrated microscopes. The tests verify compliance of the subject device to the communication protocols provided by the microscope manufacturer.	Protocols and acceptance criteria are unchanged between subject device and predicate device. All tests passed

Validation summary:

The validation comprises usability tests which ensure that the user interface can be used safely and effectively. All tests were rated as successfully passed according to their acceptance criteria. The non-clinical validation has been performed with software and equipment that are identical or equivalent to the final version of the product.