



March 1, 2018

Brainlab AG
Alexander Schwiersch
Regulatory Affairs Manager
Olof-Palme-Straße 9
81829 Munich, Germany

Re: K172820
Trade/Device Name: Microscope Navigation Software
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: January 30, 2018
Received: February 2, 2018

Dear Alexander Schwiersch:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K172820

Device Name
Microscope Navigation Software

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 1.0

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 June 20, 2017

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: [K082060](#) VECTORVISION CRANIAL

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:	New device.
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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 510(k) application supports the claim of substantial equivalence to the predicate device VectorVision Cranial.

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

Comparison of Subject Device and Predicate Device

	Predicate Device VectorVision Cranial K082060	Subject Device Microscope Navigation
Intended Use	<p>The Brainlab 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.</p> <p>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.</p> <p>Example procedures include but are not limited to:</p> <p>Cranial Procedures:</p> <ul style="list-style-type: none"> • Tumor resections • Skull base surgery • Cranial biopsies • Craniotomies/ Craniectomies 	<p>The Brainlab Navigation System - Microscope Navigation Software is a software module, that when used with a compatible computer and compatible instrument accessories, is intended as image guided planning and navigation system to enable open and minimally invasive surgery.</p> <p>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 computer. 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</p>
Brainlab Platform	Brainlab Kolibri Brainlab VectorVision	Brainlab Kick Brainlab Curve
Operating System	Windows XP	Windows 7 Windows 8.1
Application(Use)	<p>Cranial Procedures:</p> <ul style="list-style-type: none"> • Tumor resections • Skull base surgery • Cranial biopsies • Craniotomies/ Craniectomies 	<p>Cranial Procedures:</p> <ul style="list-style-type: none"> • Tumor resections • Skull base surgery • Cranial biopsies <p>Craniotomies/Craniectomies</p>
GUI	Microscope functionality integrated in the predicated device software	Microscope separated from predicated device. Microscope specific views
Tracking technology	passive, reflective markers	passive, reflective markers

	Predicate Device VectorVision Cranial K082060	Subject Device Microscope Navigation
Changes to Predicate Device:		<p>Microscope Navigation separates microscope specific functionality from the predicate device.</p> <p>Microscope Navigation adds a functionality to adjust small deviations in patient to data set registration (referred to as Registration Update or Navigation Update in the technical file). The adjustment is based on the discrepancy between data to patient overlay</p>

Verification summary:

Test	Test Method Summary	Results
Microscope focus point accuracy	The focal point crosshair is aligned to a landmark on a phantom for different working distances. The distance between landmark and focus point measured by the IGS System.	<p>The accuracy of the focus point in the focal plane is 1.2 mm +/- 0.5 mm (99th percentile 2.4 mm).</p> <p>The three-dimensional error including the distance of the focus point is measured to 1.9 mm +/- 1.0 mm (99th percentile 4.6 mm).</p>
Navigation Update	The Navigation Update is performed on a phantom for different initial registration accuracies. The accuracy of the initial accuracy is compared to the accuracy after an update on landmarks on the phantom.	<p>The Navigation Update can improve registration errors..</p> <p>For translations and rotations parallel to the focus plane the Navigation Update is accurate up to 0.8 mm +/- 0.3 mm (99th percentile 1.4 mm).</p>

The subject device is part of a set of application of an IGS system. The errors above are measured under a OR setup conditions with optimal paired-point registrations. The ground accuracy provided by the subject device is sufficient to assess navigation accuracy repeatedly throughout a procedure and identify deviations.

The subject device uses identical calibration methods. The tracking method and algorithms are identical. Instrument design and marker geometry is unchanged. The subject device is substantial equivalent to its predecessor.

Validation summary:

The validation comprises usability tests which to 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.