January 29, 2021

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

Re: K201752
Trade/Device Name: Disposable Pre-calibrated Suction
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: December 28, 2020
Received: December 31, 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)*
K201752

Device Name
Disposable Pre-Calibrated Suction

Indications for Use *(Describe)*
Disposable Pre-calibrated Suction is an accessory of the Cranial Image Guided Surgery System and intended to be used as a navigated suction device in any surgical procedure in which the use of the Cranial Image Guided Surgery System may be indicated.

Surgical example procedures include:
- Cranial resection of tumors and other lesions
- Resection of skull base tumors or other lesions
- AVM Resection

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

January 29, 2021

General Information	
Manufacturer	Brainlab AG, Olof-Palme-Str. 9, 81829, Munich, Germany
Establishment Registration	8043933
Device Name	Neurological Stereotaxic Instrument
Trade Name	Disposable Pre-calibrated suction
Classification Name	Stereotaxic instrument
Product Codes	HAW
Regulation Number	882.4560
Regulatory Class	II
Panel	Neurology
Predicate Devices and K Numbers	1. K082060 Cranial ENT IGS System 2. K092467 Disposable Stylet
Manufacturer	Brainlab AG

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

Disposable Pre-calibrated Suction is an accessory of the Cranial Image Guided Surgery System and intended to be used as a navigated suction device in any surgical procedure in which the use of the Cranial Image Guided Surgery System may be indicated.

Surgical example procedures include:
- Cranial resection of tumors and other lesions
- Resection of skull base tumors or other lesions
- AVM Resection

2. Device Description

Disposable Pre-calibrated Suction is an accessory of the Cranial IGS system and intended to be used as a navigated suction device in any surgical procedure in which the use of the Cranial IGS system may be indicated.

The Brainlab Disposable Suction is an accessory for the currently released and developed Brainlab optical IGS systems for cranial procedures. The device will be pre-calibrated, i.e. it will be automatically recognized by the system and is immediately ready to use. By tracking the flat markers attached to the integrated tracking array, the orientation of the instrument and thereby position of the tip can be located by the Brainlab optical IGS systems for cranial procedures.

The device is intended for single short term invasive use on an individual patient during a single procedure. This invasive device is used for a short-term limited contact (<24 hours) and can be in direct contact with the central nervous system (CNS) tissues and the cerebrospinal fluid (CSF).

3. Substantial Equivalence

The reusable ENT suction has the same intended use and indications for use as the Disposable Suction and hence, is considered to be a suitable primary predicate device. Furthermore, the secondary predicate - Disposable stylet, was cleared under K092467 and found to be substantially equivalent with the predicate device Cranial ENT IGS (K082060). It has comparable features in terms of: sterility, single-use and tracking technology as the Subject Device and is also intended for invasive patient contact, including CNS and CSF.

At a high level, the subject and primary predicate device are based on the following same technological elements:

a) Optical infrared light based reflective marker tracking for instrument localization
b) Suction and pointing functionality combined in one device
c) Stainless steel suction tube that is in direct contact with patient
d) Accessory to the Cranial ENT IGS system

The following technological differences exist between the subject and primary predicate device, but are all similar to the secondary predicate device:

(1) Pre-calibrated versus manual calibrated instrument
(2) Single use sterile versus reusable instrument
(3) Flat Marker versus Spherical Marker Tracking
(4) Integrated tracking array versus (de)attachable tracking array
(5) Polycarbonate handle glued to suction tube versus total stainless steel instrument

The Subject Device has larger tube diameters of 2.7 mm and 4mm when compared with the predicate device (2 mm and 3.3 mm). This larger size does not introduce an additional risk to patient safety since these dimensions are identical to suction tubes of the cleared reference device K162929 “Stryker Navigation System with CranialMap software application”. K162929 has similar indications for use as the subject device.

	Disposable Pre-calibrated Suction (Brainlab)	Posterior-Fossa Suction Tube (Stryker)	Comparison
Tube diameter	2.7mm and 4.0 mm	2.7mm and 4.0 mm	Identical

These differences do not raise any new questions of safety or effectiveness compared to the predicate device.

4. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

The substantial equivalence of the Disposable Suction is furthermore extensively verified. Technical performance has been tested on the following main aspects:

a) **Mechanical stability testing:** – mechanical stability of polycarbonate handle glued to suction tube has proven to be sufficient for intended use.
b) **Instrument tracking accuracy testing:** - instrument accuracy with flat marker technology has proven to meet accuracy requirements.
c) **Instrument system integration testing:** – pre-calibration of the Disposable Suction has proven to be effective within the Cranial IGS system.
d) **Shelf-life testing:** technical performance (mechanical stability and accuracy) have proven to still meet requirement after shelf-life.
e) **Biocompatibility testing**: – biocompatibility has been stated for all materials of the Disposable Suction, also considering the manufacturing process.
f) **Sterility testing:** sterilization validation has effectively shown that the sterility level of 10^{-6} has been reached.
g) **Sterile barrier system integrity testing**: packaging validation has proven the integrity of the sterile barriers system of the double blister packaging.

Table: Locational and angular accuracy Disposable Suction (REF 52184-01 and REF 52185-01)

	REF 52184-01		REF 52185-01	
	Locational error	**Angular error**	**Locational error**	**Angular error**
Mean	0.45 mm	0.19 °	0.51 mm	0.23 °
Standard deviation	0.11 mm	0.05 °	0.09 mm	0.06 °
95th percentile	0.93 mm	0.27 °	1.01 mm	0.31 °
99% confidence interval	0.53 mm	0.22 °	0.59 mm	0.28 °

Biocompatibility testing

The biological safety as a part of Disposable Suction basic safety has been assessed during biological safety evaluation. For a description of the used materials characterization, biological endpoint evaluation as well as for details about the performed verification tests refer to the Biological Risk Assessment by NAMSA performed according to ISO 10993-1 FDA Guidance "*Use of International Standard ISO10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*". The relevant "Biological Effect" endpoints have been assessed to identify

existing physical and/or chemical information and assess necessity of additional testing in order to demonstrate biological safety for the device acc. to its intended use..

Following biocompatibility tests have been performed (by ISO 17025 accredited laboratories) on the release candidate products manufactured, packaged and sterilized according to final manufacturing process:

- Cytotoxicity on tube test acc. to ISO 10993-5
- Cytotoxicity on handle test acc. to ISO 10993-5
- Acute Systemic Toxicity test acc. to ISO 10993-11
- Irritation test acc. to ISO 10993-10
- Pyrogen test acc. to European Pharmacopeia, 9th edition, 2016
- Pyrogen test acc. to USP 42 – NF 37
- Sensitization test acc. to ISO 10993-10
- Particle test acc. to USP [788]
- Bioburden test before and after packaging acc. to ISO 11737-1
- EO residual gas testing acc. to ISO 10993-7
- Hemolysis tests acc. to ISO 10993-4

5. Conclusion

The comparison of the Subject Device with the predicate devices shows that the Subject Device has similar functionality, intended use, technological characteristics, and typical users as the predicate devices. Verification and validation activities ensured that the design specifications are met and that the Device does not introduce new issues concerning safety and effectiveness. Hence, the Subject Device is substantially equivalent to the predicate device.