August 17, 2022

PAJUNK GmbH Medizintechnologie
Christian Quass
Director Regulatory Affairs
Karl-Hall-Str. 1
Geisingen, Baden-Wuerttemberg 78187
Germany

Re: K220897
Trade/Device Name: Disposable Brain Biopsy Needle 2.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: July 18, 2022
Received: July 18, 2022

Dear Christian Quass:

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)*
K220897

Device Name

Disposable Brain Biopsy Needle 2.0

Indications for Use *(Describe)*

The Disposable Brain Biopsy Needle 2.0 for brain biopsy is a single-use device intended for use in stereotactic and other guided biopsy of brain tissue, for example brain tumors. The Disposable Brain Biopsy Needle 2.0 is provided in a set.

The Disposable Brain Biopsy Needle 2.0 is a dual cannula device made from stainless steel. The cannula requires vacuum suction provided by a syringe to draw the tissue into the needle. The inner cannula is then rotated against the outer cannula to cut the tissue.

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.

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510(k) Summary as required by 21 CFR 807.92(c).

Date of Preparation: 2022-08-17

510 (k) Number: K220897

510(k) owner:
PAJUNK® GmbH Medizintechnologie
Karl-Hall-Str. 1
78187 Geisingen
Baden-Wuerttemberg, Germany
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-605
Establishment Registration Number:
9611612

Submitter Information/ production site:
PAJUNK® GmbH Medizintechnologie
Karl-Hall-Str. 1
78187 Geisingen
Baden-Wuerttemberg, Germany
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-605
Establishment Registration Number:
9611612

Contact:
Christian G. H. Quass
Director Regulatory Affairs, Safety Officer
Patricia Weisbrod
Regulatory Affairs Manager
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-605
E-Mail: christian.quass@pajunk.com
E-Mail: patricia.weisbrod@pajunk.com

USA Contact:
PAJUNK MEDICAL SYSTEMS
4575 Marconi Dr.
Alpharetta, GA 30005

Establishment Registration Number:
3004076349

Contact
Marco Wohnig
President
PAJUNK® Medical Systems L.P.
Phone: (770) 493-6832
Direct: (470) 448-4070
Cell: (770) 757-2449
Fax: (678) 514-3388
E-Mail: marco.wohnig@pajunk-usa.com

Device Information:

Device Name:	Disposable Brain Biopsy Needle 2.0
Components:	Needle with Marker and depth Stop Vacuum syringe Stopcock Extension tube
Sterilization method:	Ethylene Oxide disposable device supplied sterile to the end user
Contract Sterilizer:	Sterigenics Germany GmbH Kasteler straße 45 65203 Wiesbaden Germany, Hessen **Establishment Registration Number:** 3002807090
Document Control Number	*K220897*
Device Name:	Disposable Brain Biopsy Needle 2.0
Classification Name:	neurological stereotaxic instrument
Classification Reference:	*21 CFR 882.4560*
Product Code:	*HAW*
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Neurology
Predicate Device:	**K060808, Manufacturer: PAJUNK GmbH**

PAJUNK® GmbH Medizintechnologie is submitting this *510(k) for a modification* of the *Disposable Brain Biopsy Needle* cleared under K060808, intended to be brand-named Brain Biopsy Needle 2.0.

It is considered a Class II medical device as defined in 21 CFR §882.4560 neurological stereotaxic instrument, product code HAW.

Each of the devices subject to this modification of a cleared 510(k) has been validated and verified initially and is under constant batch monitoring and testing/ inspection according to the specifications cleared.

Subject to the modification is modernization of the outer appearance of the brain biopsy needle reflecting customer requirements. Furthermore this design update is intended to re-verify the state of the art in sterile needle manufacturing and navigation.

So substantial identity of the modifications is based on earlier submissions by the sponsor and verified through Design verification process.

Neither the intended use nor the indications for use are altered. Intended use as well as Indications for use, sequence of use, target patient population and user target group remain unaltered.

The fundamental technical design of the brain biopsy needle as well as of brain biopsy needles in general – sterile supply, Sedan type blunt tip, vacuum suction chamber, rotating cutting mechanism, navigation via marker, labelling – basically remains unaltered.

Performance of the subject device is verified and validated trough testing with the predicate device as well as by additional testing.

The indications for use shall be extended under a new device name.

The technique – over the needle – is rarely identified in submissions with identical indications for use. Usually it is not mentioned whether the technique of placing a catheter is “over the needle” or “through the needle”. This detail in application method does not make any difference in evaluating safety, effectiveness and efficacy of the device itself from the technological point of view.

So substantial identity of the modifications is based on earlier submissions by the sponsor and verified through Design verification process.

Performance of the subject device is verified and validated with the predicate device.

So substantial equivalence of the modifications is based on earlier submissions by the sponsor and verified through Design verification process.

Indications for use subject device:

The Disposable Brain Biopsy Needle 2.0 for brain biopsy is a single-use device intended for use in stereotactic and other guided biopsy of brain tissue, for example brain tumors. The Disposable Brain Biopsy Needle 2.0 is provided in a set.

The Disposable Brain Biopsy Needle 2.0 is a dual cannula device made from stainless steel. The cannula requires vacuum suction provided by a syringe to draw the tissue into the needle. The inner cannula is then rotated against the outer cannula to cut the tissue.

Device Description:

Biopsy needles are used to perform a biopsy of brain tissue. In the area of the blunt tip, they have a lateral biopsy window (Sedan Type) on which the biopsy is obtained.

Through navigation systems or a stereotactic frame, the biopsy window is brought to the place of interest.

Brainlab cranial navigation allows the tracking and calculation of the position of instruments with attached reflective tracking marker. It is one possible method of navigation.

There are different versions of the Biopsy Needle for following use-cases:

Guide: In the use case “Guide” the Biopsy Needle shall be used with Brainlab optical cranial navigation system with Brainlab VarioGuide, Brainlab Frameless Biopsy System or Brainlab VarioGuide Robotics. Therefore, a tracking marker array attached to Biopsy Needle shall allow the depth tracking of the instrument and calculation of the cutting window position.

Frame: In the use case “Frame” the Biopsy Needle shall be used with the Elekta Leksell stereotactic frame. A defined length and exact stop shall allow the precise inserting of the Biopsy Needle in the stereotactic frame.

Predicate Device:

The predicate device for the Brain Biopsy Needle 2.0 is the BrainPro/ BrainPro ACCESS cleared for market under K060808 and manufactured by PAJUNK® GmbH Medizintechnologie.

Determination methods and results of Substantial Equivalence Determination:

Intended Use

The intended use of brain biopsy needles is to perform Biopsy of intracranial lesions.

Indications for use Use Subject Device

The Disposable Brain Biopsy Needle 2.0 for brain biopsy is a single-use device intended for use in stereotactic and other guided biopsy of brain tissue, for example brain tumors. The Disposable Brain Biopsy Needle 2.0 is provided in a set.

The Disposable Brain Biopsy Needle 2.0 is a dual cannula device made from stainless steel. The cannula requires vacuum suction provided by a syringe to draw the tissue into the needle. The inner cannula is then rotated against the outer cannula to cut the tissue.

The Disposable Brain Biopsy Needle 2.0 is labelled as MRI conditional.

Intended Use K060808 E-Cath STIM acc. Tsui (Predicate Device)

The Pajunk BrainPro biopsy cannula for brain biopsy is a single-use device intended for use in stereotactic and other guided biopsy of brain tissue, for example brain tumors. The BrainPro is provided in a set.

The Pajunk BrainPro Biopsy Needle is a dual cannula device made from stainless steel or titanium. The cannula requires vacuum suction provided by a syringe to draw the tissue into the needle. The inner cannula is then rotated against the outer cannula to cut the tissue.

Discussion

The Intended Use of the Predicate device and of the subject device is identical.

The indications for use of the Predicate device and of the subject device is identical. In order to provide state of the art information, MRI information has been added. The subject device is substantially equivalent to the predicate device.