February 22, 2023

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

Re: K230201
Trade/Device Name: Disposable Pre-calibrated Brain Biopsy Needle 2.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: January 24, 2023
Received: January 25, 2023

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 -S
Digitally signed by Adam D. Pierce -S
Date: 2023.02.22 16:36:12 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230201

Device Name

Disposable Pre-calibrated Brain Biopsy Needle 2.0

Indications for Use *(Describe)*

The Disposable Pre-calibrated Biopsy Needle 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 Pre-calibrated Biopsy Needle is provided in a set.
The Disposable Pre-calibrated Biopsy Needle 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 Pre-calibrated Biopsy Needle is labelled as MRI conditional.

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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K230201: 510(k) Summary as required by 21 CFR 807.92(c).

Date of Preparation: 2023-02-10

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Device Information:

Device Name:	**Disposable Pre-Calibrated Brain Biopsy Needle 2.0**
Components:	Needle with Marker and depth Stop Vacuum syringe Stopcock Extension tube
Sterilization method:	Ethylene Oxide
Contract Sterilizer:	disposable device supplied sterile to the end user Sterigenics Germany GmbH Kastler Straße 45 65203 Wiesbaden Germany, Hessen **Establishment Registration Number:** 3002807090
Document Control Number	*K230201*
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:	**K220897, Manufacturer: PAJUNK GmbH** Disposable Brain Biopsy Needle 2.0
Reference Device:	**K201752, Disposable Pre-Calibrated Suction**

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Indications for use

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 Pre-Calibrated Biopsy Needle is labelled as MRI conditional.

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 **Disposable Brain Biopsy Needle 2.0** 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.

Substantial Equivalence Discussion

The Intended Use and Indications for Use of the predicate and subject devices are identical except for MRI-labelling. MR Conditional is added to the labeling for the subject device.

In order to substantiate the MR Conditional labelling change, testing was conducted on the Disposable Brain Biopsy Needle 2.0 to demonstrate that it is safe to be used in an MR environment outside of a 5 Gauss line. In addition, the Reference Device, Disposable Precalibrated Suction, cleared under K201752 has been chosen to demonstrate MR compatibility.

Side-by-side comparison table

Characteristics	Subject Device K230201 Disposable Brain Biopsy Needle 2.0 Pajunk® GmbH Medizintechnologie	Predicate Device K220897 Disposable Brain Biopsy Needle 2.0 Pajunk® GmbH Medizintechnologie	*Result of comparison, if necessary with rationale*
Biocompatibility	ISO 10993-1 compliant material & set components		Identical
Labeling	21 CFR and European Medical Devices Directive compliant MR Unsafe	21 CFR and European Medical Devices Directive compliant **MR Conditional**	Labeling is different because of the addition of the MR Conditional Labeling. MRI testing included in this submission.
Packaging	Packed in a hard blister package consisting out of GGG PET foil and Tyvek (heat sealed) or medical paper	Packed in a hard blister package consisting out of GGG PET foil and Tyvek (heat sealed) or medical paper	identical
Overall design: Set components	Needles: a) Hubs: - clear or coloured Polymer needle hub - Connectivity: Luer Lock b) Glue needle is glued in hub c) Tubings: - Stainless steel - with graduation rings Depth stop: - Coloured polymer	Needles: a) Hubs: - clear or coloured Polymer needle hub - Connectivity: Luer Lock b) Glue needle is glued in hub c) Tubings: - Stainless steel - with graduation rings Depth stop: - Coloured polymer	identical
Technology	Mechanical end stops for situations: Biopsy chamber open/closed Additionally, visually shown by combination of markers in the handle	Mechanical end stops for situations: Biopsy chamber open/closed Additionally, visually shown by combination of markers in the handle	identical

Characteristics	**Subject Device** **K230201 Disposable Brain Biopsy Needle 2.0** **Pajunk® GmbH Medizintechnologie**	**Predicate Device** **K220897 Disposable Brain Biopsy Needle 2.0** **Pajunk® GmbH Medizintechnologie**	***Result of comparison, if necessary with rationale***
principles of operation	Suction of tissue in the window through a vacuum created with the syringe. Turn cut by windows rotated against one another.	Suction of tissue in the window through a vacuum created with the syringe. Turn cut by windows rotated against one another.	identical
Materials	Body contacting parts: Stainless Steel Indirect contacting parts (handle): Polycarbonate	Body contacting parts: Stainless Steel Indirect contacting parts (handle): Polycarbonate	identical

Performance Testing

Testing was conducted on the Disposable Brain Biopsy Needle 2.0 to demonstrate that no magnetically induced displacement is detectable under the given contitions for the device being labelled as “MR Conditional”.

Test	Test Method Summary	Result
Measurement of magnetically induced displacement force on “Disposable Pre-calibrated Biopsy Needle 2.1 x 257 mm” in the magnetic resonance environment of a 3 Tesla MR scanner.	According to ASTM F2052-15 “Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment” The medical device is suspended by a string in an MR system at a location near the entrance to the bore and on the axis of the bore. In order to increase the measurement sensitivity, this location shall be chosen so that the spatial gradient of the field strength is within 20 percent of the maximum value of the spatial gradient on the axis of the bore. The angular deflection of the string from the vertical is measured. If the device deflects less than 45°, then the deflection force induced by the MR System’s magnetic field is less than the force on the device due to gravity (its weight).	No magnetically induced displacement was detectable for the test object “Disposable Pre-calibrated Biopsy Needle 2.1 x 257 mm” used within this test and in the described MR environment of a 3 Tesla Siemens Magnetom Vida MR scanner.

Testing was conducted on the Disposable Brain Biopsy Needle 2.0 to demonstrate that it is safe to be used in an MR environment if a 5 Gauss line (0.5 mTesla) is clearly marked on the floor around the MR scanner.

Conclusion:

The comparison between the predicate devices and the subject device of this submission demonstrates that the subject devices are the same as the predicate device and substantially equivalent in technical description to those devices already cleared for market and therefore demonstrated to be as safe and effective as the legal predicate devices.