August 26, 2020

Minnetronix Neuro, Inc.
% Prithul Bom
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K202072
Trade/Device Name: MindsEye Expandable Port
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-Retaining Retractor For Neurosurgery
Regulatory Class: Class II
Product Code: GZT
Dated: July 24, 2020
Received: July 27, 2020

Dear Prithul Bom:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202072

Device Name
MindsEye™ Expandable Port

Indications for Use *(Describe)*
The Expandable Port is intended to provide access, allow visualization of the surgical field, and retraction of soft tissue during neurological cranial surgery.

The device is indicated for use in surgery during which subcortical access is required.

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

In accordance with 21 CFR 807.92 and FDA Guidance Document *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* dated July 28, 2014, Minnetronix Neuro provides this 510(k) Summary.

5. 510(k) NUMBER: K202072

5.1 SUBMITTER INFORMATION

Company Name:	Minnetronix Neuro, Inc.
Company Address:	1625 Energy Park Drive, St. Paul MN 55108
Company Phone:	(651) 917-4060
Company Facsimile:	(651) 917-4066
Contact Person:	Matt Adams, VP / GM
Date Summary Prepared:	August 25, 2020

5.2 DEVICE IDENTIFICATION

Device Trade Name:	MindsEye™ Expandable Port
Common Name:	Neurological surgical port
Classification Name:	Self-retaining retractor for neurosurgery (21 CFR 882.4800, Product Code GZT)
Device Class:	Class II
Advisory Panel:	Neurological Devices Panel

5.3 IDENTIFICATION OF PREDICATE DEVICE

The predicate device for the MindsEye Expandable Port is the Nico® BrainPath® (K172433) with reference to the Vycor VBAS (K060973).

5.4 DEVICE DESCRIPTION

The MindsEye Expandable Port is a single use, minimally invasive intracranial medical device designed to provide access and allow visualization to the surgical field while retracting subcortical soft tissues during neurological cranial surgery. Its design allows the user to place

the port while collapsed in its minimal form for atraumatic access to the subcortical space. After placement, the port can be expanded radially to create a working channel to the target surgical location. The user is able to expand the port to the desired working channel diameter appropriate for the surgical plan then collapse the port upon surgical completion for safe removal. The working channel diameter may be adjusted as needed by the user throughout surgery.

The MindsEye device is expected to be used in conjunction with other standard, commercially available intracranial medical devices, such as an aspirator, micro/endo/exoscope, irrigation, electrosurgical systems/tools and/or hemostatic agents. In addition, MindsEye is compatible with existing optical navigation systems for accurate target acquisition and may be attached to other commercial retraction systems according to user preference.

The MindsEye device is made of biocompatible, medical grade materials (metals and polymers) with no software or electrical components. The MindsEye device and its components are provided sterile and not reusable.

MindsEye is comprised of the following components and is available in three lengths (Table 1).

- Port with attached Sheath
- Obturator and Guide
- Optional Support System consisting of support clips, post, and legs

Table 1: MindsEye Expandable Port Sizes

Model Number	Port Length (mm)
N-EXP1A-052	52
N-EXP1A-062	62
N-EXP1A-077	77

5.5 INDICATIONS FOR USE

The Expandable Port is intended to provide access, allow visualization of the surgical field, and retraction of soft tissue during neurological cranial surgery.

The device is indicated for use in surgery during which subcortical access is required.

5.6 TECHNOLOGICAL CHARACTERISTICS COMPARISON

While there are expected technological differences due to the ability of MindsEye to be placed in collapsed form then expanded (dilatable working channel) as compared to the static size working channel offered by the predicate; the overall indication for use, principles of operation and placement as well as general size of the device are similar to the predicate and reference devices.

Similar Characteristics:
Like the predicate and reference devices, the MindsEye port is placed using an obturator for atraumatic introduction. Placement can be performed using a commercial optical navigation system often utilized for surgical planning. The obturator is then removed leaving a working channel to allow for visualization and surgical access within the brain tissue. MindsEye can accommodate a minimum inner diameter (i.e. working channel) of 6mm to a maximum diameter of 21mm. The inner diameter range of MindsEye (6 – 21mm) is smaller then or within the diameter range of the predicate and references devices (11 – 28mm). Similarly, MindsEye is available in three port lengths (52 – 77mm) to accommodate various surgical locations which is also within the length range of the predicate and references devices (30 – 95mm). The transparent sheath allows users to see cerebral vasculature, structures and tissue adjacent to the sheath and accommodates the visualization preferences (i.e. use of an endoscope, microscope, loupes, etc.) of the user during surgery. Finally, MindsEye is compatible with typical adjunct surgical instruments such as larger retraction systems, aspirators, forceps, bipolar and other electrosurgical and hemostasis devices.

Different Characteristics:
To allow for the radial dilation of the MindsEye port, it was designed with a flexible, compliant sheath and controlled mechanism to expand and contract as intended. This is the primary difference from the predicate and reference devices which have a hard, static size sheath. To achieve this, different materials of manufacture are used as compared to the predicate and reference devices, however comprehensive biocompatibility testing was performed to maintain the safety profile of the device. Characterization and performance testing were completed to provide assurance that the sheath of the MindsEye device is robust enough to withstand the normal conditions of brain surgery. A summary of the predicate and reference device comparison is provided in Table 2.

Table 2: Predicate Comparison

	Predicate NICO BrainPath	**MindsEye Expandable Port**	**Reference** Vycor VBAS
510(k) Number	K172433	Not yet assigned	K060973
Intended Use	To provide for access and allow for visualization of the surgical field during brain and spinal surgery.	Provide access and allow visualization to the surgical field and to retract soft tissue during neurological cranial surgery.	Same as predicate
Device Components			
Sheath Lengths	L: 50, 60, 75, 95mm	L: 52, 62, 77mm	TC model: L: 30, 50, 70, 90mm
Sheath Inner Diameter Options	ID: 11, 13.5mm	ID Expandable: 6 - 21mm	TC model: ID: 12, 17, 21, 28mm
Obturator Tip Length	L: 8mm and 15mm	L: 9 mm	Unknown
Principle of Primary Operation			
	Consists of an “obturator-like” component and a “sheath-like” component which are assembled, inserted, and disassembled to provide corridor access	Same as Predicate	Same
Operation and Placement			
	Handheld and can be assisted by third-party navigation (if desired)	Same as Predicate	Same
Shipping Configuration			
	Obturator and sheath packaged and shipped separately and paired during surgical case	The obturator and sheath are packaged and shipped together ready for use	The port and introducer are packaged assembled ready for use
Reusable or Single Patient Use			
	Single patient use and reusable	Single patient use only	Single patient use only
Method of Sterilization			
	Disposables: Gamma Reusables: Autoclave/hydrogen peroxide gas plasma	EO Reusables: None	Gamma Reusables: None

	Predicate NICO BrainPath	**MindsEye Expandable Port**	**Reference** Vycor VBAS
Biocompatibility			
	Demonstrated based on externally communicating device in direct contact with tissue/bone/dentin for a limited duration	Same as Predicate	Same
Materials of Manufacture			
	Obturator: Aluminum Sheath: COC	Sheath – Chronoprene 5A Guide - ABS Obturator – 303 SS Support system – 303 SS	Unknown
Cross Sectional Analysis of Obturator / Sheath			
	Obturator / Sheath combination has a circular cross section	Obturator / sheath (port) combination has a circular cross section when placed Sheath (port) has a hexagonal cross section when dilated	Various depending on model from circular to elliptical
General Shape of Obturator Tip			
	Distal end of obturator has a conical shape with a rounded tip and no opening	Same as Predicate	Various depending on the model
Third-Party Instrumentation			
	Obturator component interfaces with third party instruments	Same as Predicate	Same
Navigation Locking Mechanism			
	Included as part of the obturator	Same as Predicate	None
Surface of Sheath			
	Inner diameter and horizontal proximal surface of the knurled ring are textured	Inner and outer surface of sheath is non-reflective, transparent, and flexible	Port is transparent and non-compliant
Proximal End of Sheath			
	Updated knurled ring with concave geometry to reduce optical glare, still includes holes, slots and tabs.	The proximal end has a non-reflective head and dial for port expansion with tabs that can be used to connect to the support system	Unknown

5.7 SUMMARY OF TESTING

A series of non-clinical tests, biocompatibility, sterility, and shelf life testing were performed to demonstrate that MindsEye met the applicable design and performance requirements to support a determination of substantial equivalence related to the safety and effectiveness of the MindsEye device as compared to the predicate and reference devices.

Table 3: Non-Clinical Testing Summary

Non-Clinical Test	MindsEye Component	Result
Cytotoxicity: MEM elution	All potential patient contacting components	Pass – non-cytotoxic
Sensitization: (Maximum)	All potential patient contacting components	Pass – non-sensitizer
Irritation: (Intracutaneous Reactivity)	All potential patient contacting components	Pass – non-irritant
Acute System Toxicity	All potential patient contacting components	Pass
Material Mediated Pyrogenicity	All potential patient contacting components	Pass
Packaging and Shelf Life • shipping/distribution simulation, • environmental conditions, aging, visual packaging inspection, • bubble and seal strength packaging testing, • environmental and shipping simulation	All	Pass
Sterilization • B&F testing, • BI for SAL 10-6, • Endotoxin testing	All	Pass
Specification Review	All	Pass
Damage Resistance	Sheath	Pass

5.8 CONCLUSION

A review of the risk assessment, biocompatibility and other non-clinical testing, in addition to demonstrated compliance with recognized standards, have established that the MindsEye Expandable Port does not raise different questions of safety or effectiveness for the described intended use when compared to the predicate and reference devices. Therefore, the results of these analyses provide reasonable assurance that the MindsEye Expandable Port has a similar safety and effectiveness profile as compared to the predicate and supports a determination of substantial equivalence.