January 14, 2021

Vycor Medical Inc.
% Maria Griffin
Senior Consultant
mdi Consultants, Inc.
55 Northern Blvd., Ste 200
Great Neck, New York 11021

Re: K202694
Trade/Device Name: Vycor Medical Viewsite Brain Access System ("VBAS") and VBAS with Alignment Clip ("VBAS AC") (together the "VBAS Family")
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-Retaining Retractor For Neurosurgery
Regulatory Class: Class II
Product Code: GZT
Dated: December 10, 2020
Received: December 15, 2020

Dear Maria Griffin:

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)*
K202694

Device Name
Vycor Medical Viewsite Brain Access System ("VBAS") and VBAS with Alignment Clip ("VBAS AC") (together the "VBAS Family")

Indications for Use *(Describe)*
The Vycor Viewsite Brain Access System (VBAS) is intended to provide for access and allow for visualization of the surgical field during brain and spine surgery.

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

The assigned 510(k) number is: **K202694**

1. Submitter's Identification:

VYCOR MEDICAL INC.
951 Broken Sound Parkway, STE 320
Boca Raton, FL 33487

Phone: 561-558-2020
Fax: 561-620-2545

Company Contact: Mr. Theo Novak, Director of Engineering and R&D

Date Summary Prepared: January 14, 2021

2. Trade Name of the Device:

Vycor Medical Viewsite Brain Access System ("VBAS") and VBAS with Alignment Clip ("VBAS AC") (together the "VBAS Family")

Regulation Number:	882.4800
Regulation Name:	Self-retaining retractor for neurosurgery
Regulatory Class:	Class II
Product Code:	GZT
Panel:	Neurology

3. Predicate Device Information:

Vycor ViewSite Surgical Access System (VBAS) K060973

4. Device Description:

The Vycor Medical Surgical Access System (VBAS) includes a family of retractor devices of varying shapes and sizes designed for providing diagnostic and surgical access to various portions of the brain and spinal region. The subject device is comprised of the modified version of the predicate device cleared under #K060973 together with the optional Alignment clip (A)C component.

The models designated with post characters "AC" includes the Alignment Clip ("AC") included separately in the packaging. This is available for all models other than the 6mm size. The AC may be optionally attached to aid in centering third party navigational and image guided system ("IGS") pointers or probes ("pointer").

Like the predicate, the subject device consists of an introducer and port. The port and introducer are packaged assembled and ready for use. Upon insertion of the device, the introducer is removed and the port is left in place. The introducer has a length greater than the port. The smooth and soft tapered introducer works to

spread apart the brain or other portions of delicate tissue. Upon removal of the introducer, the port provides a hollow working channel allowing the surgeon access to the target tissues.

The AC optional component was designed to make the VBAS easier to use with IGS by enabling the IGS pointer to be centered and held in place:

- Designed to accommodate a range of commonly-used pointers
- Securely clips onto the VBAS device when used
- Provides insertion direction to center the pointer in the device and ensure vertical alignment
- Provides locking mechanism to securely hold the pointer in place and therefore enable the pointer and VBAS to be one integrated unit freeing up one of the surgeon's hands

5. Indications for Use:

The Vycor Viewsite Brain Access System (VBAS) is intended to provide for access and allow for visualization of the surgical field during brain and spine surgery.

6. Technological Comparison to the Predicate Device:

The original VBAS design (Predicate) differs from the VBAS/AC Subject device family in the following ways:

1. Adding a cup in distal end of the introducer to seat and center a navigational pointer. Replacement of through-hole in distal end of the introducer for fluid passage with a small hole and flow channels, providing the same flow performance.
2. Packaging and configuration: Replacement of double pouch sterile packaging system with double tray sterile packaging system.
3. Model size range: Expansion of elliptical diameters from initial 17 and 21mm to 6, 12, 17, 21 and 28mm.
4. Addition of the "AC" models, which includes the optional alignment clip in all, but the 6mm versions.

The similarities of the predicate and subject device are listed below:

1. Same indications for use and intended use.
2. Same User Population and patient population.
3. Same sterilization method (Gamma radiation)
4. Same body contacting materials are used.
5. Same retraction method.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The following testing was conducted to prove safety and effectiveness as well as substantial equivalence to the predicate device:

Test	Test Method Summary	Results
Shelf Life Testing / Functional Testing	Devices were functionally tested to meet device specifications after a third party performed accelerated aging for the claimed shelf life of 7 years.	The devices passed the testing. Acceptance criteria were met.
Packaging for Terminally Sterilized Medical Devices	Packaging Validation was performed per ISO 11607-1:2019 and ISO 11607-2:2019 to assure packaging integrity	Devices met acceptance criteria.
Human factors / Usability Testing	Usability tests with neurosurgeons were performed in a simulated clinical environment covering the clinical workflow with the subject device to assure device is used as intended.	Device met acceptance criteria.
Sterilization Validation	Validate the minimum gamma dose to achieve sterilization per ISO 11137-2:2013	Device met acceptance criteria
Biocompatibility	N/A	Device utilized the identical patient contacting materials as the predicate device; therefore new testing was not performed.

Accelerated Aging / Shelf life testing / Functional testing

Usability/Human Factors testing per the FDA guidance document *"Applying Human Factors and Usability Engineering to Medical Devices"*

The following National and International Standards were utilized for testing the subject device:

Packaging for Terminally Sterilized Medical Devices ISO 11607-1:2019
Packaging for Terminally Sterilized Medical Devices ISO 11607-2:2019
Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose ISO 11137-2:2013

The subject device and the predicate device have the same indications for use, substantially equivalent performance specifications and design requirements, are used and operate in the same way and in the same environment, and use the same materials, manufacturing and sterilization processes.

The subject device met all acceptance criteria for the tests listed above and no new issues of safety or effectiveness were raised.

Therefore, Vycor concludes that the subject device and the predicate device are substantially equivalent.

8. Discussion of Clinical Tests Performed:

Not applicable

9. Conclusions:

We conclude that the VBAS with Alignment Clip ("VBAS AC") has been shown to be as safe and effective as the predicate device and does not raise different questions of safety and effectiveness than the predicate device and is substantially equivalent to the predicate device.