June 3, 2025

Phasor Health, LLC
Ray King
Chief Executive Officer
8944 Kirby Drive
Houston, Texas 77054

Re: K243205
Trade/Device Name: EVAC
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: Class II
Product Code: JXG
Dated: December 19, 2024
Received: December 19, 2024

Dear Ray King:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2025.06.03 14:15:55 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243205

Device Name

EVAC

Indications for Use *(Describe)*

Phasor EVAC™ is indicated when access to and evacuation of a cranial subacute or chronic hematoma or hygroma is necessary. The EVAC system is intended for drainage of subdural fluid accumulations such as hygromas and chronic or subacute hematomas to an external suction reservoir. The EVAC system is also intended for draining air and fluids from the subdural space immediately following craniotomy procedures performed to remove a chronic or subacute subdural hematoma.

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

A. Device Description

Category	Comments
Sponsor	Phasor Health, LLC, Ray King, 8944 Kirby Drive, Houston, TX 77054, U.S.A. (832) 982-1234
Correspondent Contact Information	Ray King 8944 Kirby Drive, Houston, TX 77054, U.S.A. (832) 982-1234
Device Common Name	Central nervous system fluid shunt and components
Device Regulation & Name	21 CFR 882.5550
Classification & Product Code	Class II, JXG
Device Proprietary Name	EVAC

Predicate Device(s) Information:

Predicate Device(s)	(1) Subdural Evacuation Port System (SEPS) Cranial Access Kit; (2) Phasor Drill
Predicate Device Manufacturer(s)	(1) Medtronic, Inc., (2) Phasor Health, LLC; respectively
Predicate Device Common Name	(1) Central nervous system fluid shunt and components [subdural fluid drainage system]; (2) Powered simple cranial drills, burrs, trephines, and their accessories; respectively
Predicate Device Notification #	(1) K042359; (2) K161704
Predicate Device Classification & Name	(1) 21 CFR 882.5550; (2) 21 CFR 882.4310; respectively
Predicate Device Classification & Product Code:	Class II for each of (1) JXG & (2) HBE, respectively

B. Date Summary Prepared: May 21, 2025

C. Description of Device

Phasor EVAC™ subdural evacuation system is indicated when access to the subdural space and evacuation of a cranial subacute or chronic hematoma or hygroma is necessary. The EVAC system consists of surgical instruments and accessories used for draining subdural

fluid accumulations such as hygromas and liquid-state subdural hematomas to an external suction reservoir without touching the brain. Utilizing a minimally invasive technique, the EVAC system components are designed to promote gradual brain re-expansion by creating a low homogeneous negative pressure throughout the subdural space as fluid is drained to an external suction reservoir.

D. Indications for Use

Phasor EVAC™ is indicated when access to and evacuation of a cranial subacute or chronic hematoma or hygroma is necessary. The EVAC system is intended for drainage of subdural fluid accumulations such as hygromas and chronic or subacute hematomas to an external suction reservoir. The EVAC system is also intended for draining air and fluids from the subdural space immediately following craniotomy procedures performed to remove a chronic or subacute subdural hematoma."

E. Comparison of the Technological Characteristics

	Application Device	**Predicate Device**	**Predicate Device**	**Impact on Substantial Equivalence**
Company	Phasor Health, LLC	Medtronic, Inc.	Biotex, Inc. (now Phasor Health, LLC)	N/A
Regulation Number	21 CFR 882.5550	21 CFR 882.5550	21 CFR 882.4310	includes both predicates
Product Code	JXG (Class II)	JXG (Class II)	HBE (Class II)	together, comparable to both devices
Intended Use & Indications for Use	EVAC™ is indicated when access to and evacuation of a cranial subacute or chronic hematoma or hygroma is necessary. The EVAC system is intended for drainage of subdural fluid accumulations such as	SEPS™ is indicated when access to and evacuation of a cranial subacute or chronic hematoma or hygroma is necessary. The Subdural Evacuating Port System Cranial Access Kit is intended for	The Phasor™ Drill is a sterile, single-use, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone.	Taken together, comparable to both devices

	hygromas and chronic or subacute hematomas to an external suction reservoir. The EVAC system is also intended for draining air and fluids from the subdural space immediately following craniotomy procedures performed to remove a chronic or subacute subdural hematoma."	drainage of subdural fluid accumulations such as hygromas and chronic or subacute hematomas to an external suction reservoir. The Subdural Evacuating Port System Cranial Access Kit is also intended for draining air and fluids from the subdural space immediately following craniotomy procedures performed to remove a chronic or subacute subdural hematoma."		
Technology				
Drill power source	Batteries	Manual	Batteries	comparable when considered together
Bolt	screws into skull at threaded end	screws into skull at threaded end	N/A	comparable bolts
Drain reservoir connected to Bolt via Tubing	100cc connected with silicon tubing	100cc connected with silicon tubing	N/A	comparable

Occlusion relief/additional aspiration	Side port	puncture tubing via needle aspiration	N/A	no impact

F. Summary of Supporting Data

EVAC™ has the same intended use, patient population, and classification as the predicate. At a high level, the subject and predicate devices are based upon the following technological elements, when the two predicates are taken together:

* Sterile packaged for single use, and disposable;
* Phasor Drill operates on battery power, as per the predicate (same mechanism as itself);
* Bolt screws into the skull in the same manner, with comparable inner diameter;
* Reservoir connects via similar tubing as the first predicate

The following technical characteristics of the subject device differ from the predicate device:

* Taken by itself, SEPS utilizes a disposable single-use sterile manually operated drill, whereas EVAC™ utilizes a disposable single-use sterile battery-powered drill (with same characteristics as the second predicate, the Phasor Drill);
* for relief of occlusion or need for additional aspiration, SEPS utilizes a needle placed through tubing (which punctures the tubing), whereas EVAC™ accomplishes similar feature and goal via a side port precluding need for puncture of tubing;
* SEPS™ is sterilized using EO, whereas EVAC™ is sterilized with EO (kit and reservoir) and gamma (Phasor Drill, tubing, and bolt) with individual packages placed together into the same shelf carton after respective sterilization.

The proposed device does not differ from the predicates taken together in any manner which would negatively impact the safety or effectiveness of the device.

G. Discussion of Performance Testing

Various tests including for biocompatibility, packaging, sterility, safety, and performance were conducted and passed successfully. The Phasor™ Drill has been previously cleared, and any other components were justified as comparable and/or supported by documentation with adequate performance. Specifically, testing for a closed system with firm purchase into bone was established and verified by testing. No clinical testing was needed or performed otherwise.

H. Conclusion

The performance and design validation testing conducted on the EVAC™ device on the bench demonstrated that it performs equivalent to the stated predicates that are currently

marketed individually for the same intended use. The proposed device, comprised of the elements noted above, demonstrates that it should perform as safely and effectively as the predicate device(s).