



November 5, 2025

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

Re: K252514

Trade/Device Name: EVAC-MRI  
Regulation Number: 21 CFR 882.5550  
Regulation Name: Central nervous system fluid shunt and components  
Regulatory Class: Class II  
Product Code: JXG  
Dated: August 7, 2025  
Received: August 11, 2025

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](mailto: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: 2025.11.05  
09:14:28 -05'00'

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

## Indications for Use

510(k) Number (if known)

K252514

Device Name

Phasor EVAC-MRI

Indications for Use (Describe)

Phasor EVAC-MRI is indicated when access to and evacuation of a cranial subacute or chronic hematoma or hygroma is necessary. The Phasor EVAC-MRI system is intended for drainage of subdural fluid accumulations such as hygromas and chronic or subacute hematomas to an external suction reservoir. The Phasor EVAC-MRI 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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**Phasor EVAC-MRI™****A. Device Description**

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

**Predicate Device(s) Information:**

<b>Predicate Device(s)</b>	(1) Phasor EVAC; (2) Subdural Evacuation Port System (SEPS) Cranial Access Kit; (3) Integra Cranial Access Kit INSHITH (cited by K042359, with variant INS7250 without any other related predicate)
<b>Predicate Device Manufacturer(s)</b>	(1) Phasor Health, LLC (2) Medtronic, Inc.; (3) Integra Lifesciences
<b>Predicate Device Common Name</b>	(1) Central nervous system fluid shunt and components [subdural fluid drainage system] (2) subdural fluid drainage system; (3) Cranial Access Kit
<b>Predicate Device Notification #</b>	(1) K243205 (2) K042359; (3) K961113 cited by K042359 as predicate without any other separate K# for Integra Cranial Access Kit
<b>Predicate Device Classification &amp; Name</b>	21 CFR 882.5550 for predicate (1) and (2); 21 CFR 882.4300 for predicate (3)
<b>Predicate Device Classification &amp; Product Code:</b>	Class II, JXG for predicates (1) and (2); Class II, HBG for predicate (3)

**B. Date Summary Prepared:** October 2, 2025

### C. Description of Device

Phasor EVAC-MRI™ 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 Phasor EVAC-MRI™ 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 Phasor EVAC-MRI™ 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. The completeness of the Phasor EVAC-MRI™ system saves time and eliminates the need to gather supplies; this convenience can be critical in an emergency situation.

### D. Indications for Use

Phasor EVAC-MRI™ is indicated when access to and evacuation of a cranial subacute or chronic hematoma or hygroma is necessary. The Phasor EVAC-MRI™ system is intended for drainage of subdural fluid accumulations such as hygromas and chronic or subacute hematomas to an external suction reservoir. The Phasor EVAC-MRI™ 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 Technological Characteristics

	<u>Application Device</u>	<u>Predicate Device</u>	<u>Predicate Device</u>	<u>Predicate Device</u>	<u>Impact on Substantial Equivalence</u>
<b>Company</b>	Phasor Health, LLC	Phasor Health, LLC	Medtronic, Inc.	Integra Lifesciences citing Clinical Neurosystems	N/A
<b>Regulation Number</b>	21 CFR 882.5550	21 CFR 882.5550	21 CFR 882.5550	21 CFR 882.4300	Same as predicates (1) and (2)
<b>Product Code</b>	JXG (Class II)	JXG (Class II)	JXG (Class II)	HBG (Class II)	Same as predicates (1) and (2)
<b>Intended Use &amp; Indications for Use</b>	Phasor EVAC-MRI™ is indicated when access to and evacuation of a cranial subacute or chronic hematoma or hygroma is necessary. The Phasor EVAC-MRI™ system is intended for drainage of subdural fluid	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	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 drainage of subdural fluid accumulations such as hygromas and chronic or subacute hematomas to an external suction	The drill is intended to be used with an external drainage and monitoring system in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF, and to monitor ICP. The drill is	Same as predicates (1) and (2)

	accumulations such as hygromas and chronic or subacute hematomas to an external suction reservoir. The Phasor EVAC-MRI™ 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.	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.	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." SEPS contains drugs including chlorhexidine, lidocaine, and povidone-iodine ointment.	intended for single use only. (Integra INSHITH is cited as a predicate by SEPS, K042359, and INS7250 is a variant of INSHITH which contains saline without separate K# being required).	
<b>Technology</b>					
<b>Drill power source</b>	Batteries	Batteries	Manual	Manual	Same drill as primary predicate
<b>Bolt</b>	screws into skull at threaded end	screws into skull at threaded end	screws into skull at threaded end	N/A (Cranial Access Kit only)	Same as predicate, no change.
<b>MR Safety</b>	MR Conditional for Bolt	MR Unsafe for all components	MR Unsafe for all components	Unknown	Same bolt used as predicate
<b>Drain reservoir connected to Bolt via Tubing</b>	100cc connected with silicon tubing	100cc connected with silicon tubing	100cc connected with silicon tubing	N/A (no drain provided, as only cranial access kit)	Same as predicate, no change.
<b>Occlusion relief/additional aspiration</b>	Side port	puncture tubing via needle aspiration	puncture tubing via needle aspiration	N/A ( as cranial access kit only)	Same as predicate, no change.

## F. Summary of Supporting Data

EVAC-MRI™ has the same intended use, patient population, and classification as the predicate. At a high level, the subject and predicate device are based upon the following technological elements:

- \* 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, as per the predicate.

\* Reservoir connects via similar tubing as per the predicate

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

\*Magnetic Resonance Safety of predicate device EVAC™ is MR Unsafe, whereas subject device Phasor EVAC-MRI™ is labelled MR Conditional with testing performed for the bolt.

\*The kit items of the predicate device (Medtronic SEPS) contains comparable drugs with the exception of saline (which is covered by predicate Integra INSHITH or Integra IN7250), and the subject device contains saline as an additional drug in the kit without requiring a separate 510(k); the subject device also does not contain ointment.

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

### **G. Discussion of Performance Testing**

Various tests including biocompatibility, packaging, sterility, safety, and performance were conducted and passed successfully which is the same as the predicate Phasor EVAC. 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. Magnetic Resonance Safety testing successfully addresses magnetically induced, force, torque, image artifact and RF induced heating per ASTM standards. No clinical testing was needed or performed otherwise.

### **H. Conclusion**

The performance and design validation testing conducted on the Phasor EVAC-MRI™ 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 as effectively as the predicate device(s).