November 21, 2025

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

Re: K252696
Trade/Device Name: LEGACY
Regulation Number: 21 CFR 882.4300
Regulation Name: Manual Cranial Drills, Burrs, Trephines, and Their Accessories
Regulatory Class: Class II
Product Code: HBG
Dated: October 31, 2025
Received: October 31, 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 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,

XIAOLIN ZHENG
-S

For Jaime Raben, Ph.D.
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.

510(k) Number *(if known)*
K252696

Device Name
LEGACY

Indications for Use *(Describe)*
The Phasor LEGACY drill is a sterile, single-use, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone.

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 Phasor Health, LLC

LEGACY™

A. Device Description

Category	Comments
Sponsor	Phasor Health, LLC Ray King CEO 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	Cranial Drill
Device Regulation & Name	21 CFR 882.4300; Manual Cranial Drills, Burrs, Trephines, and Their Accessories
Classification & Product Code	Class II, HBG
Device Proprietary Name	LEGACY

Predicate Device(s) Information:

Predicate Device(s)	(1) Clinical Neuro Systems Interchangeable Bit Cranial Drill (2) Phasor Drill
Predicate Device Manufacturer(s)	(1) Clinical Neuro Systems; (2) Phasor Health, LLC; respectively
Predicate Device Common Name	(1) Cranial drill; (2) Powered simple cranial drills, burrs, trephines, and their accessories; respectively
Predicate Device Premarket Notification #	(1) K961113; (2) K161704; respectively
Predicate Device Classification & Name	(1) 21 CFR 882.4300; (2) 21 CFR 882.4310; respectively
Predicate Device Classification & Product Code:	Class II for each of (1) HBG & (2) HBE, respectively

B. Date Summary Prepared: November 20, 2025

C. Description of Device

Phasor LEGACY drill is indicated for drilling of cranial bone by licensed and credentialed medical professionals. The LEGACY drill is manually powered by rotating the handle in a clockwise manner, and is a standalone drill driver without bits or any other items included. It is compatible via an AO quick-connect mechanism with similar AO-interface drill bits, ≤ 6.35 mm diameter and ≤ 70 mm usable length (protruding from the housing). The device is gamma-sterilized and composed of plastic housing with stainless steel shaft.

D. Indications for Use

The Phasor LEGACY drill is a sterile, single-use, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone.

E. Comparison of the Technological Characteristics

	Application Device (K252696)	**Predicate Device (K961113)**	**Predicate Device (K161704)**	**Impact on Substantial Equivalence**
Company	Phasor Health, LLC	Clinical Neuro Systems	Biotex, Inc. (now Phasor Health, LLC)	N/A
Regulation Number	21 CFR 882.4300	21 CFR 882.4300	21 CFR 882.4310	Same as predicate (K961113)
Product Code	HBG (Class II)	HBG (Class II)	HBE (Class II)	Same as predicate (K961113)
Intended Use & Indications for Use	The Phasor LEGACY drill is a sterile, single-use, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone.	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 intended for single use only.	The Phasor™ Drill is a sterile, single-use, disposable device intended for use on adult patients during neurosurgical procedures for drilling of cranial bone.	Same overall intended use as the predicate devices for drilling cranial bone
Target Population and Use Environment	For adults used in healthcare facilities	For adults used in healthcare facilities	For adults used in healthcare facilities	Same as predicates
Anatomical Site	Head	Head	Head or Extremities	Same as predicates
Where Used	Hospital	Hospital	Hospital	Same as predicates
Energy Used and/or Delivered	Manually operated	Manually operated	Battery (DC current) operated	Same as predicate (K961113)
Human Factors	Hand-crank drill mechanism	Hand-crank drill mechanism	Switch (on/off) operation	Same as predicate (K961113)
Design	Hand-held	Hand-held	Hand-held	Same as predicates
Performance	Rotates at hand-crank speed	Rotates at hand-crank speed	Rotates at set speed (est. 400-800 RPM)	Same as predicate (K961113)
Standards Met	ANSI/AAMI/ISO 11137-2:2013/(R)2019 & A1:2022, ANSI/AAMI/ISO 11737-1:2018 & A1:2021, ISO 11737-2, ASTM D4332-22, D4169-22, ASTM F88/F88M-21, ASTM F2096, ISO 15223-1, ISO 11607-1	Not listed	ISO 10993-17:2002 and ISO 10993-18:2005; ASTM F1980-07 (Reapproved 2011), ASTM D4169-14, ASTM F88/F88M-09, ASTM F2096-11 .	Same standards used as predicate (K161704) except differs in biocompatibility since no patient-contacting components are provided for the subject device

Materials	Plastic (ABS), Steel	Plastic, Steel	Plastic, Steel, Electrical Flex Cable, Batteries, Copper (for motor)	Similar to predicate (K961113), and same as predicate (K161704)
Biocompatibility	Not applicable due to no direct patient-contacting part(s)	Tested and passed for patient-contacting parts	Tested and passed for patient-contacting parts	Differs from predicates since no patient-contacting parts provided
Compatibility with the Environment and Other Devices	Compatibility with AO quick-connect drill bits (not included) established	Compatibility with chuck-bit mechanism (bit included with device)	N/A, as bit connected to motor already in initial version	Comparable to predicate (K961113) as both devices use mechanical means to retain drill bit and benchtop mechanical testing passed
Sterility	Provided sterile	Provided sterile	Provided sterile	Comparable to predicates
Electrical Safety	N/A, as no electrical components involved	N/A, as no electrical components involved	Established as compliant to respective standards at approval	Comparable to predicate device (K961113) in that both devices do not have electrical components
Mechanical Safety	Established via performance testing for intended use, without impairment of device during function	Established via performance testing for intended use, without impairment of device during function	Established via performance testing for intended use, without impairment of device during function	Comparable to predicate devices
Radiation Safety	MR Unsafe	MR Unsafe	MR Unsafe	Same as predicates
Technology				
Drill Power Source	Manual	Manual	Batteries	Same as predicate (K961113)
Sterilization Validation	Sterile (Irradiation)	Sterile (EO Sterilization)	Sterile (Irradiation)	The subject device and predicate devices were validated to recognized standards for sterilization and passed the validation testing

F. Summary of Supporting Data

Sterilization validation performed for gamma radiation conforming to ANSI/AAMI/ISO 11137-2:2013/(R)2019 & A1:2022, ANSI/AAMI/ISO 11737-1:2018 & A1:2021, ANSI/AAMI/ISO 11737-2:2019, ISO 13004:2022.

Packaging validation performed conforming to ASTM D4332, ASTM D4169, ASTM F88/F88M-21, ASTM F2096, ISO 11607-1.

Symbols in labeling conform to ISO 15223-1.

G. Discussion of Performance Testing

The Phasor LEGACY™ drill performed adequately to drill holes in a simulated cranial bone material in a comparable manner as would be expected with the predicate device. No clinical testing was needed or performed otherwise.

A human factors study was also performed to evaluate the LEGACY drill. The objective of the human factors study was to evaluate whether users could safely and effectively perform all user tasks associated with identifying, engaging, operating, and disposing of the LEGACY™ drill under expected use conditions. The study demonstrated that all user tasks were completed successfully without errors that would impact safety or effectiveness for the involved intended users, uses, and use environments, supporting substantial equivalence to the predicate device.

H. Conclusion

Comprehensive testing, including packaging, sterility, and performance evaluations, was conducted on the Phasor LEGACY™ drill, with all results meeting acceptance criteria or adequately justified. The performance and design validation data demonstrate that the Phasor LEGACY™ drill is substantially equivalent to the predicate device in terms of safety and effectiveness.