



October 31, 2025

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

Re: K252060

Trade/Device Name: Green

Regulation Number: 21 CFR 882.4310

Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, And Their Accessories

Regulatory Class: Class II

Product Code: HBE

Dated: October 2, 2025

Received: October 2, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce -S Digitally signed by
Adam D. Pierce -S
Date: 2025.10.31
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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

Indications for Use

510(k) Number (if known)

K252060

Device Name

GREEN

Indications for Use (Describe)

Phasor GREEN Drill is a re-sterilizable drill driver (for use on one or more patients, up to 10 total holes), with separately packaged single-use sterilized drill bit assembly -- 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.

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Phasor GREEN™
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	Powered simple cranial drills, burrs, trephines, and their accessories
Device Regulation & Name	21 CFR 882.4310
Classification & Product Code	Class II, HBE
Device Proprietary Name	PHASOR GREEN

Predicate Device(s) Information:

Legally Marketed reference device used to support substantial equivalence in terms of cleaning and sterilizing the equipment using Vaporized Hydrogen Peroxide (VHP).

Predicate Device(s)/ Reference Devices(s)	Phasor Drill / Stryker Reprocessed Pulse Oximeter Sensor
Predicate Device/ Reference device Manufacturer(s)	(1) Phasor Health, LLC, (2) Stryker Sustainability Solutions
Predicate Device Common Name / Reference Device Common Name	(1) Powered simple cranial drills, burrs, trephines, and their accessories; (2) Oximeter
Predicate Device Notification # / Reference Device Notification #	(1) K161704; (2) K211138
Predicate Device Classification & Name; Reference Device Classification & Name	(1) 21 CFR 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories; (2) 21 CFR 870.2700 Oximeter.
Predicate Device Classification & Product Code / Reference Device Classification & Name	Class II for each of (1) HBE & (2) NLF, respectively

B. Date Summary Prepared: October 2, 2025

C. Description of Device

The Phasor™ GREEN Drill is composed of 2 items: (1) a re-sterilizable, non-rechargeable battery-operated Phasor Green Driver (made of plastic housing, capable of drilling up to 10 total holes in one or more patients) in conjunction with (2) a separately packaged, single-use Phasor Green Drill Bit Assembly comprised of a steel bit (of 6.35-mm or less), plastic adapter, and polybag secured using latex-free bands. The device is for drilling cranial or orthopedic bone, by prescription only and used by qualified users, with (1) Drill Driver (provided non-sterile) for

sterilization using vaporized hydrogen peroxide (VHP) prior to use at user facility and (2) Drill Bit Assembly provided gamma-sterilized for single-use respectively.

D. Indications for Use

Phasor GREEN™ Drill is a re-sterilizable drill driver (for use on one or more patients, up to 10 total holes), connected to a separately-packaged single-use sterilized drill bit assembly -- for use on adult patients during neurosurgical procedures for drilling of cranial bone.

E. Comparison of the Technological Characteristics

	Application Device	Predicate Device	Reference Device	Impact on Substantial Equivalence
Company	Phasor Health, LLC	Phasor Health, LLC	Stryker	N/A
Regulation Number	21 CFR 882.4310	21 CFR 882.4310	21 CFR 870.2700	No impact
Product Code	HBE (Class II)	HBE (Class II)	NLF (Class II)	No impact
Intended Use & Indications for Use	Phasor GREEN™ Drill is a re-sterilizable drill driver (for use on one or more patients, up to 10 total holes), with separately packaged single-use sterilized drill bit assembly -- for use on adult patients during neurosurgical procedures for drilling of cranial or orthopedic bone.	Phasor GREEN™ Drill is a re-sterilizable drill driver (for use on one or more patients, up to 10 total holes), with separately packaged single-use sterilized drill bit assembly -- for use on adult patients during neurosurgical procedures for drilling of cranial or orthopedic bone.	The sensor is indicated for single patient use for continuous noninvasive arterial oxygen saturation and pulse rate monitoring.	Comparable to predicate device.
Technology				
Driver Power Source	Single-use Lithium non-rechargeable Batteries	Single-use Lithium non-rechargeable Batteries;	No onboard battery or power source; contains sensors.	Same as predicate device
Performance Characteristics	Drills bone	Drills bone	optical sensor transmits light to photodetector that detects signal transmission. The signal transmission is processed by the Pulse Oximeter to provide SpO2 and pulse rate.	comparable performance to predicate device
Drill bit	440C	440C	N/A	Same as predicate device
Activation buttons	Forward/Reverse button on housing	Forward/Reverse button for driver	N/A no activation required	comparable to reference device

Biocompatibility	Yes	Yes	N/A	Same as predicate device
Electrical components including connections, wiring, switches, etc.	Motor, wiring, on/off switch, forward/reverse switch, batteries 18V	Motor, wiring, on/off switch, forward/reverse switch, batteries 18V	N/A	Identical
Sterility Status at Shipping	(1) Drill Driver shipped non-sterile to user's facility, to be sterilized using VHP by user prior to initial and each subsequent use (2) Drill Bit Assembly shipped sterile (using gamma sterilization) to user	Sterile	Sterile	comparable to reference device
Sterilization Method	(1)VHP for the Drill Driver at user facility prior to each use; (2) Gamma irradiation for Drill Bit Assembly	Gamma irradiation	Vaporous Hydrogen Peroxide	comparable to reference device
Cleaning and Sterilization Testing Standard(s) Met	(1) ISO 22441 for VHP for Drill driver (2) ISO 11607-1 for Drill Bit Assembly	ISO 11607-1	ISO 17665-1 (utilizing VHP, but noting K211138 preceded the ISO 22441 release date of August 26, 2022)	Met testing to noted standard for Application Device

F. Summary of Supporting Data

Phasor GREEN™ has the same intended use (while being multi-use vs. single-use), material composition, manufacturing process, manufacturer, patient population, classification, and initial packaging as the predicate. Moreover, it has the same sterilization method as the reference device. Phasor Drill had already been utilized as a "quick-connect" per justification based upon documentation, compatible with bits of the same range. Otherwise, the subject and predicate devices are based upon the following technological elements, when the predicate and reference device are taken together:

- * Drilling function into cranial bone in the same manner, with same drill bit diameter size ranges as supported for the predicate device;
- * Both the GREEN DRILL BIT DRIVER and predicate Phasor Drill are sterilized in the same manner (gamma sterilization);
- * Both the GREEN DRILL BIT DRIVER and predicate Phasor Drill are intended for single-use, and are disposable after the single use.

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

- * Phasor GREEN DRIVER is a multi-use (<= 10 uses), compared to the single-use Phasor Drill;
- * Phasor GREEN DRIVER is vaporized hydrogen peroxide (VHP) sterilized vs. Gamma sterilized for the Phasor Drill.

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

G. Discussion of Performance Testing

Post-respective sterilization using VHP and gamma for the GREEN Driver and Drill Bit Assembly, respectively, performance testing of 10 holes with each Driver and bit were accomplished within the time period needed, similar to the predicate Phasor Drill.

H. Conclusion

The performance and design validation testing conducted on Phasor GREEN™ device on the bench demonstrated that it performs comparably to the stated predicate and reference device that are currently marketed individually for the similar intended use. The proposed device, comprised of the elements noted above, demonstrates that it should perform as safely and as effectively as the predicate device.