July 9, 2025

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

Re: K250505
Trade/Device Name: EZ-Fiducials
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: June 9, 2025
Received: June 9, 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: 2025.07.09 09:43:44 -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
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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)*
K250505

Device Name
EZ-Fiducials

Indications for Use *(Describe)*
Phasor EZ-Fiducials is intended to provide fixed reference point(s) in patients requiring stereotactic surgery in conjunction with CT imaging with the included screws placed using the included EZ-Driver (electric screwdriver) or manual screwdriver exclusively for each.

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

EZ-FIDUCIALS™

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	subdural fluid drainage kit
Device Regulation & Name	21 CFR 882.4560
Classification & Product Code	Class II, HAW
Device Proprietary Name	EZ-FIDUCIALS

Predicate Device(s) Information:

Predicate Device(s)/ Reference Devices(s)	Navigus Unibody Fiducial Marker System/ OsteoMed Pinnacle Driver
Predicate Device/ Reference device Manufacturer(s)	(1) Medtronic, Inc., (2) OsteoMed; respectively
Predicate Device Common Name	(1) Navigus Unibody Fiducial Marker System; (2) Battery-operated drill/driver; respectively
Predicate Device Notification #	(1) K033619; (2) K162542
Predicate Device Classification & Name	(1) 21 CFR 882.4560; (2) 21 CFR 882.4310; respectively
Predicate Device Classification & Product Code:	Class II for each of (1) HAW & (2) HBE, respectively

B. Date Summary Prepared: July 8, 2025

C. Description of Device

Phasor EZ-FIDUCIALS™ provide fixed reference points during neurosurgical procedures. The device is composed of 3 items, all single-use, provided gamma-sterilized, and placed within the same primary packaging (sealed Tyvek tray within a shelf carton):
(1) Screws: Each of the four provided titanium screws is identical, with specific dimensions of each EZ-Fiducials screw as follows: screwhead circular shape screwhead with square-shaped engagement, non-threaded shaft diameter 2.9mm and length 15mm, threaded shaft diameter (major threads) 1.98mm, thread length 5mm; no protective caps are provided, and the screws should exclusively be utilized in conjunction with the screwdrivers (manual or EZ-Driver) provided together in the same tray (and with no other screwdriver);
(2) Manual Screwdriver: handheld, to be solely used with the screws provided, not intended for use with any other screws;
(3) EZ-driver: (electric, handheld, non-rechargeable battery-operated screwdriver, without software, single-use for solely tightening or loosening the provided screws exclusively, not intended for use with any other screws).

D. Indications for Use

Phasor EZ-Fiducials is intended to provide fixed reference point(s) in patients requiring stereotactic surgery in conjunction with CT imaging with the included screws placed using the included EZ-Driver (electric screwdriver) or manual screwdriver exclusively for each.

E. Comparison of Technological Characteristics

	Application Device	**Predicate Device**	**Reference Device**	**Impact on Substantial Equivalence**
Company	Phasor Health, LLC	Medtronic, Inc.	Osteomed Pinnacle	N/A

510(k)	Pending	K033619	K162542	Comparable
Regulation Number	21 CFR 882.4560	21 CFR 882.4560	21 CFR 882.4310	screws comparable to predicate device; accessory screwdriver similar to reference device
Product Code	HAW	HAW	HBE	comparable for predicate device
Device Class	II	II	II	Comparable
Product Code	HAW (Class II)	HAW (Class II)	HBE (Class II)	comparable for predicate device
Intended Use & Indications for Use	Intended Use: Phasor EZ FIDUCIALS™ are intended for use as fixed reference points for presurgery CT imaging for patients requiring stereotactic surgery. Indications for Use: Phasor EZ-Fiducials is intended to provide fixed reference point(s) in patients requiring stereotactic surgery in conjunction with CT imaging with the included screws placed using the included EZ-Driver (electric screwdriver) or manual screwdriver exclusively for each.	Intended Use: The Medtronic Unibody Models FM-4007, FM-4010, and FM-4013 Bone Fiducials are intended for use as fixed reference points for presurgery CT imaging for patients requiring stereotactic surgery. Indications for Use: Navigus Unibody Fiducial Marker System is intended to provide fixed reference point(s) in patients requiring stereotactic surgery in conjunction with CT imaging.	Intended Use (and Indications for Use): The PINNACLE Driver is intended for driving screws and for drilling into bone, in conjunction with cranial surgical procedures.	taken together, comparable to both devices
Technology				
Screwdriver Power Source	Single-use Lithium non-rechargeable Batteries (for EZ-Driver); Manually operated for "Manual Screwdriver" included	Manual	Disposable, lithium, single use, sterile battery	comparable when considered together
Performance Characteristics	screws into skull at threaded end	screws into skull at threaded end	N/A	comparable screws to predicate device
Screw	screws into skull at threaded end	screws into skull at threaded end	N/A	comparable screws to predicate device
Activation buttons	Forward/Reverse button for EZ-Driver; N/A for manual screwdriver which can be turned in forward or reverse direction	N/A for manual screwdriver which can be turned in forward or reverse direction	Forward/Reverse buttons for Driver	comparable to reference device
Insertion material	bone	bone	bone	Same
Screw Sizes/Insertion	2.0mm	1.6mm	1.2mm, 1.6mm, 2.0mm	Comparable
Biocompatibility	Yes	Yes		
Sterile	Yes	Yes		

Single-use	Yes	Yes		
Speed of Electric Driver	30rpm	N/A	120rpm	different, but ability to drive screw supported by performance testing
Performance Testing Standard(s) Met for Screws	ASTM F543-23	No standard referenced	No standard referenced	Met testing to noted standard for Application Device

F. Summary of Supporting Data

EZ-FIDUCIALS™ has the same intended use, patient population, and classification as the predicate. Accessory screwdrivers are comparable to the reference device noted. The subject and predicate devices are based upon the following technological elements, when the predicate and reference devices are taken together:

* Sterile packaged for single use, and disposable.
* OsteoMed Pinnacle Driver operates on single-use battery power, as per the reference predicate (lithium-ion battery);
* Bone screws purchase into the skull in similar manner.

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

* Navigus Unibody bone fiducials are provided without an electric or manual screwdriver (although one would be needed) for insertion;
* Navigus Unibody supplies "protective cap" and "screwdriver guide" (which are optional items, not required to the indications or intended use);
* Osteomed Pinnacle driver is a high-speed driver with screwdriving and drilling capabilities, but otherwise comparable to EZ-Driver in that either can be used to drive screws (or remove them). Moreover, while Osteomed Pinnacle screwdriver can be used electrically or manually (in the still setting with power off to turn screws), Phasor EZ-Driver as part of EZ-Fiducials may be used similarly in power-on or power-off manual settings, but the EZ-Fiducials manual screwdriver is provided additionally to serve this same purpose of manual screw turning.
* Navigus Unibody bone fiducials is sterilized using EO, whereas EZ-FIDUCIALS™ is sterilized with gamma with the manual screwdriver, electric screwdriver and bone fiducials/screws sealed together in a tray packaged in a shelf carton.

The proposed device does not appear to 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 biocompatibility, packaging, sterility, safety, and performance have been validated with justifications as comparable and/or supported by documentation with adequate performance. Specifically, testing for a deflection of bone screws using a Coordinate Measuring Machine (CMM) with firm purchase into bone simulant was established and verified by testing. Further testing was performed to ensure the EZ-Fiducials screws was compliant with the ASTM F543-23 standard, with the electric screwdriver also tested and performing adequately (per report "02670-019011-1" including Table 6). No clinical testing was needed or performed otherwise.

H. Conclusion

The predicate device was cleared based upon bench testing alone. The performance and design validation testing conducted on the EZ-FIDUCIALS™ device on the bench demonstrated that it performs equivalent to the stated predicate and reference device 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.