June 4, 2025

PhysCade, Inc.
Grace Li
Head of QA/RA
2100 Geng Road, Suite 210
Palo Alto, California 94303

Re: K250749
Trade/Device Name: PhysCade System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: March 12, 2025
Received: March 12, 2025

Dear Grace Li:

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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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)*

K250749

Device Name

PhysCade System

Indications for Use *(Describe)*

The PhysCade System is intended for the analysis, display, and storage of cardiac electrophysiological data and maps for analysis by a physician.

The clinical significance of utilizing the PhysCade System to help identify areas with intra-cardiac atrial electrograms exhibiting local early activated potentials and other features of interest during atrial arrhythmias has not been established by clinical investigations.

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.

Submitter's information

PhysCade, Inc.
2100 Geng Road, Suite 210
Palo Alto, CA 94303
United States

Contact: Raphael Michel
President & CEO
PhysCade, Inc.
2100 Geng Road, Suite 210
Palo Alto, CA 94303

Classification The classification for the new device is listed below.

21 CFR Reference	Product Code	Class	Generic Device Name	Classification Description
§870.1425	DQK	II	Computer, Diagnostic, Programmable	Programmable diagnostic computer

New device The new device's indications for use statement is listed in the table below.

Device Name	Indications for Use
PhysCade System	The PhysCade System is intended for the analysis, display, and storage of cardiac electrophysiological data and maps for analysis by a physician. The clinical significance of utilizing the PhysCade System to help identify areas with intra-cardiac atrial electrograms exhibiting local early activated potentials and other features of interest during atrial arrhythmias has not been established by clinical investigations.

Predicate device The predicate device for the PhysCade System is shown in the table below.

K Number	Product Code	Predicate Device Name	Indications for Use
K201298	DQK	Volta Medical VX1	The VX1 assists operators in the real-time manual annotation of 3D anatomical and electrical maps of human atria for the presence of multipolar intra-cardiac atrial electrograms exhibiting spatiotemporal dispersion during atrial fibrillation or atrial tachycardia. The clinical significance of utilizing the VX1 software to help identify areas with intra-cardiac atrial electrograms exhibiting spatiotemporal dispersion for catheter ablation of atrial arrhythmias, such as atrial fibrillation, has not been established by clinical investigations.

Device description

The PhysCade™ System (PhysCade) is an artificial intelligence (AI) enabled device intended to assist clinicians in their management of patients with heart rhythm disorders (arrhythmias). PhysCade is a medical decision support system which post-processes electrograms (EGMs) collected inside the heart during electrophysiology (EP) mapping procedures using compatible diagnostic EP catheters. The PhysCade software has advanced algorithms that analyze the collected EGMs to provide information on regions of interest in the heart that may be useful to the clinician to support clinical decisions together with other available patient-related information.

PhysCade provides specialized analyses of data from a compatible multipolar catheter. The primary output (coPILOT) indicates the predominant earliest site of activation relative to the catheter electrode array. Supporting outputs include determining activation times of successive beats in the EGM signal on each electrode (coMAP), voltage at each electrode, signal quality, and sequences of propagation over multiple beats of the arrhythmia on the catheter.

The PhysCade System consists of a computer workstation, display, and custom software and is not connected to other devices or medical equipment.

PhysCade is intended to be used in the cardiac electrophysiology lab, outside the sterile field. PhysCade is intended to be operated by nurses, technicians, physicians, or other personnel who are trained and approved by each treating facility to work in the electrophysiology lab.

PhysCade uses AI algorithms that were developed and tested using datasets with the following characteristics:

Features	Development Cohort		Test Cohort
	Training	Tuning	
Number of electrograms	~15M	~5M	~5M
Number of patients	174	62	109
Age	67.91 ± 8.80	68.97 ± 8.26	67.10 ± 7.66
AF Type Non-Paroxysmal, n (%) Paroxysmal, n (%)	 124 (71.26) 50 (28.74)	 45 (72.58) 17 (27.42)	 82 (75.23) 27 (24.77)
Female, n (%)	31 (17.82)	6 (9.68)	29 (26.61)
Racial category (non-white), n (%)*	36 (20.93)	16 (25.81)	20 (20.20)
BMI, kg/m^2	29.45 ± 5.72	29.45 ± 6.46	29.67 ± 6.67
CHADS2VASC	2.57 ± 1.57	2.65 ± 1.36	2.70 ± 1.66
LA Size Enlarged, n (%)*	90 (55.21)	32 (55.17)	54 (58.70)
Coronary disease, n (%)	35 (20.11)	19 (30.65)	27 (24.77)
Myocardial Infarct, n (%)	10 (5.75)	6 (9.68)	6 (5.50)
Hypertension, n (%)	128 (73.56)	47 (75.81)	70 (64.22)
Diabetes Mellitus, n (%)	32 (18.39)	9 (14.52)	21 (19.27)
Prior Stroke/TIA, n (%)	16 (9.20)	3 (4.84)	8 (7.34)
All data complete except for *minor missingness in the categorical variables of racial category (disclosed in N=172/174 in training, N=62/62 in tuning and 99/109 in test cohorts), and left atrial enlargement (variable recorded in N=163/174 in training, N=58/62 in tuning and 92/109 in test cohorts).			

Characteristics - comparison with predicate device

The table below lists the characteristics for both the new and predicate devices.

ATTRIBUTE	SUBJECT DEVICE PhysCade System	PREDICATE DEVICE Volta VX1 K201298	COMPARISON
Indications for use	The PhysCade System is intended for the analysis, display, and storage of cardiac electrophysiological data and maps for analysis by a physician. The clinical significance of utilizing the PhysCade System to help identify areas with intra-cardiac atrial electrograms exhibiting local early activated potentials and other features of interest during atrial arrhythmias has not been established by clinical investigations.	The VX1 assists operators in the real-time manual annotation of 3D anatomical and electrical maps of human atria for the presence of multipolar intra-cardiac atrial electrograms exhibiting spatiotemporal dispersion during atrial fibrillation or atrial tachycardia. The clinical significance of utilizing the VX1 software to help identify areas with intra-cardiac atrial electrograms exhibiting spatiotemporal dispersion for catheter ablation of atrial arrhythmias, such as atrial fibrillation, has not been established by clinical investigations.	The PhysCade System has the same intended use and similar indications for use as the predicate device. Both devices assist in review and analysis of electrical maps of the human atria. The predicate device indications for use, while broader, identifies electrical activity in areas of interest for catheter ablation of atrial arrhythmias.
Regulation	21 CFR 870.1425	21 CFR 870.1425	Same
FDA Product code	DQK	DQK	Same
Classification	Programmable diagnostic computer, 21 CFR §870.1425	Programmable diagnostic computer, 21 CFR §870.1425	Same
Population	Adults	Adults	Same
System Type	Signal processing based atrial mapping system	Signal processing based atrial mapping system	Same
Display(s)	Color monitor	Color monitor	Same
Control	Standard keyboard / mouse	Standard keyboard / mouse	Same

ATTRIBUTE	SUBJECT DEVICE PhysCade System	PREDICATE DEVICE Volta VX1 K201298	COMPARISON
Inputs Required	Intra-cardiac atrial electrograms that are recorded with catheters, and surface ECG signals amplified and input to the PhysCade System on which they are displayed.	Intra-cardiac atrial electrograms that are recorded with catheters, amplified and redirected to an acquisition system on which they are displayed.	The subject and predicate devices analyze intra-cardiac atrial electrograms. The PhysCade System also inputs the ECG signal to assist in the analysis of intracardiac electrograms, which does not alter the intended use.
Connections	A USB flash drive is used to export data from compatible analog-to-digital converter systems and import data into the PhysCade System.	A connection cable is used to connect the data acquisition system with an Advantech PCI-1713U analog-to-digital converter, which transmits the acquired information to a nearby computer that hosts the VX1 software.	Both devices digitize intra-cardiac data for input to their analysis systems. While the subject and predicate devices use different brands of analog-to-digital converters, and the subject device uses a USB drive for export while the predicate device uses a connector cable, the transfer of data is equivalent.
Principal Mapping Output	Displays adjudications as visual cues after analyzing intra-cardiac atrial electrograms using signal processing techniques.	Displays adjudications as visual cues after analyzing intra-cardiac atrial electrograms in real-time using signal processing techniques.	The predicate device and subject device provide adjudications during a procedure. While the predicate device inputs data from a connector cable, the subject device uploads data from a USB flash drive. Both systems provide output during an EP study to support clinical decision-making.

ATTRIBUTE	SUBJECT DEVICE PhysCade System	PREDICATE DEVICE Volta VX1 K201298	COMPARISON
Map Types Generated	The operator is provided with a display of the multipolar electrode map indicating locations where wave direction is earliest, and markings of electrogram activation time, by the PhysCade System during recordings of atrial fibrillation.	Real-time Dispersed Electrogram (DE) subtype of multipolar electrogram map- The operator is provided with display of the electrode locations where dispersed or non-dispersed electrograms have been recorded during atrial fibrillation or atrial tachycardia.	Both the subject and predicate devices generate multipolar maps of their analysis of intra-cardiac data. The predicate device focuses on dispersed electrograms, while the subject device focuses on direction to the earliest site. Both devices produce a multipolar map of electrical locations of interest during atrial fibrillation.
Compatible Catheters	Any compatible catheter meeting the requirements listed below: <u>Compatibility requirements:</u> **Mapping catheter:** - Electrode size: 0.5 mm to 3 mm - Inter-electrode spacing: 2 to 10mm (edge-to-edge) - Number of selected electrodes: between 8 and 64 - Electrode configuration: a spatial grid of at least 2 electrodes along each side (e.g., 4X4, 8X8)	Any compatible catheter meeting the requirements listed below: <u>Compatibility Requirements:</u> **Mapping catheter:** - Electrode size: 1 mm - Inter-electrode Spacing: 2 to 3 mm - Number of selected dipoles: 10 **Coronary sinus catheter:** - Electrode size: 1 mm - Interelectrode Spacing: 2 to 3 mm - Number of selected dipoles: 5	Both devices are compatible with catheters that are defined in their labeling which have been validated with their corresponding algorithms. The predicate device can also be used with Coronary Sinus catheters but this is not required for the subject device analysis.

ATTRIBUTE	SUBJECT DEVICE PhysCade System	PREDICATE DEVICE Volta VX1 K201298	COMPARISON
Data Acquisition System	The PhysCade System works with three data acquisition systems: - LabSystem Pro Acquisition (Boston Scientific), - MacLab CardioLab Acquisition System (General Electric), - Ensite NavX/Precision System (Abbott)	The VX1 works with two data acquisition systems: - LabSystem Pro Acquisition (Boston Scientific), - MacLab CardioLab Acquisition System (General Electric)	The subject device is compatible with the same two data acquisition systems as the predicate device and adds compatibility with a third data acquisition system - Ensite. These 510(k) cleared data acquisition systems all produce digitized and amplified signals that are numerically similar.
Hardware Design and Materials	Off-the-shelf computer and monitor, connection cable, acquisition system, proprietary software algorithm.	Off-the-shelf analog / digital converter, computer and monitor, connection cable, acquisition system, proprietary software algorithm.	Both devices use off-the-shelf hardware with a proprietary software algorithm.

Performance testing

The PhysCade System was subjected to extensive non-clinical testing including rigorous verification and validation testing. The testing consisted of:

- Software/Firmware and cybersecurity verification and validation testing confirmed that the subject device meets the design input requirements and specifications
- Design Verification testing confirmed that the subject device hardware meets performance specifications.
- Design Validation confirmed that the AI/ML system is accurate for its intended use.
- Usability testing demonstrated that the subject device meets the user needs specifications.

The PhysCade System was developed and tested in accordance with IEC 62304 Edition 1.1 2015-06.

Guidance documents referenced for testing

The following guidance documents were referenced for testing:

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

- Content of Premarket Submissions for Management of Cybersecurity in Medical Device
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Off-The-Shelf Software Use in Medical Devices
- Applying Human Factors and Usability Engineering to Medical Devices
- Good Machine Learning Practice for Medical Device Development: Guiding Principles

Conclusion

A comparison has been conducted of the intended use/indications for use, performance characteristics, design features, technological/functional characteristics, and labeling for the PhysCade System. Intended to provide the physician with additional information that supports standard clinical practice, no new or different questions of safety or effectiveness are raised.

The PhysCade System has the same intended use as the predicate device. Testing results demonstrate that minor differences in the technological characteristics do not raise questions of safety and effectiveness. Thus, the PhysCade System is substantially equivalent to the Volta VX1 predicate device (K201298).