December 4, 2025

Vektor Medical, Inc.
Mihir Naik
Vice President, Quality Assurance and Regulatory Affairs
9255 Towne Centre Dr., Suite 840
San Diego, California 92121

Re: K252429
Trade/Device Name: Vektor Computational ECG Mapping System (vMap®)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: November 5, 2025
Received: November 6, 2025

Dear Mihir Naik:

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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K252429 |

Please provide the device trade name(s).

Vektor Computational ECG Mapping System (vMap®)

Please provide your Indications for Use below.

The Vektor Computational ECG Mapping System (vMap®) is intended for the analysis, display, and storage of cardiac electrophysiological data and maps for analysis by a physician.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252429

# 510(k) Summary

Prepared on: 2025-11-05

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Vektor Medical, Inc. |
| Applicant Address | 9255 Towne Centre Dr Suite 840 San Diego CA 92121 United States |
| Applicant Contact Telephone | 858-518-1393 |
| Applicant Contact | Mr. Mihir Naik |
| Applicant Contact Email | mnaik@vektormedical.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Vektor Computational ECG Mapping System (vMap®) |
| Common Name | Programmable diagnostic computer |
| Classification Name | Computer, Diagnostic, Programmable |
| Regulation Number | 870.1425 |
| Product Code(s) | DQK |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K211546 | Vektor Computational ECG Mapping System (vMap®) | DQK |
| K223516 | VX1+ | DQK |
| K242016 | EnSite™ X EP System | DQK |
| K232161 | DeepRhythm Platform | DPS |

## Device Description Summary

21 CFR 807.92(a)(4)

vMap is a standalone Software as a Medical Device (SaMD) application. vMap receives electrocardiogram (ECG) data (from other FDA-authorized medical devices) acquired non-invasively from the patient's body surface and processes these signals using proprietary algorithms to transform body surface measurements into cardiac electrical data. vMap utilizes this data to generate 2D cardiac information and 3D color maps that illustrate cardiac electrical features for physician analysis. vMap is intended for use in clinical environments, including electrophysiology (EP) laboratories and hospital settings.

vMap includes a main user application that provides an intuitive user interface to guide clinicians through the mapping workflow. vMap enables users to:

a. Create and manage mapping cases through an organized case management system.
b. Upload ECG data acquired from compatible recording systems.
c. Identify arrhythmias to be mapped, including marking arrhythmic beats on ECG plots.
d. Generate two-dimensional (2D) and three-dimensional (3D) heatmaps representing likely arrhythmia source locations.
e. View and interact with mapping results within the software interface.
f. Export results for integration with external electroanatomic mapping systems (e.g., Carto™, Ensite™).
g. Produce detailed case reports summarizing the mapping session and findings.

vMap SaMD operates on compatible general-purpose computing hardware that includes an off-the-shelf processing unit, monitor, keyboard and mouse. The vMap software is compatible with equivalent hardware components.

Principles of Operation:
vMap receives electrocardiographic signals acquired non-invasively from the body surface. The ECG signals are used in proprietary algorithms to transform the measured body surface signals into cardiac signals. These algorithms leverage simulated focal or rotor activity from simulated source locations across the entire heart. vMap analyzes focal-based mechanisms for focal-type and anatomical reentry-type arrhythmias (Focal Atrial Tachycardia, Premature Atrial Complex, Atrial Pacing, Ventricular Tachycardia, Premature Ventricular Complex, Ventricular Pacing, and Atrioventricular Reentrant Tachycardia, Typical Atrial Flutter and Atypical Atrial Flutter), and rotor-based mechanisms for fibrillation-type arrhythmias (Atrial Fibrillation and Ventricular Fibrillation). vMap software utilizes this data to provide various 2D cardiac information and interactive 3D color maps, including cardiac electrical features, for analysis by a physician.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Vektor Computational ECG Mapping System (vMap®) is intended for the analysis, display, and storage of cardiac electrophysiological data and maps for analysis by a physician.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The Vektor Computational ECG Mapping System (vMap®) is a non-invasive, software-driven tool designed for beat-by-beat, multi-chamber, two-dimensional (2D) and three-dimensional (3D) analysis and mapping of the heart. This Software as a Medical Device (SaMD) receives electrocardiogram (ECG) data acquired non-invasively from the patient's body surface and processes these signals using proprietary algorithms to transform body surface measurements into cardiac electrical data. vMap utilizes this data to generate 2D cardiac information and 3D color maps that illustrate cardiac electrical features for physician analysis.

The following devices were selected in support of the presented substantial equivalence rationale:
- Proposed Device: Vektor Medical, Inc. - Vektor Computational ECG Mapping System (vMap®)
- Primary Predicate Device: Vektor Medical, Inc. - Vektor Computational ECG Mapping System (vMap®) (K211546)
- Secondary Predicate Device 1: Volta Medical - VX1+ (K223516)
- Secondary Predicate Device 2: Abbott Medical - EnSite™ X EP System (K242016)
- Reference Device: Medicalgorithmics S.A – DeepRhythm Platform (K232161)

The proposed vMap has the same intended use and Indications for Use as the Vektor Computational ECG Mapping System (vMap) (K211546) (primary predicate device). Both vMap and the primary predicate device analyze patient-specific surface ECG data to generate electrical activity maps indicative of cardiac electrical activity, using computational modeling techniques. Additionally, the proposed vMap shares key technological similarities with the primary predicate device, including analysis, display, and storage of cardiac electrophysiological data for physician review.

## Technological Comparison

21 CFR 807.92(a)(6)

The following presents a detailed discussion of the proposed and predicate devices with regard to intended use, anatomical sites, patient population, product labeling, performance testing, technological characteristics and safety characteristics.

Intended Use/Indications for Use:
The proposed vMap maintains identical intended use and Indications for Use as its primary predicate device, intended for the analysis, display, and storage of cardiac electrophysiological data and maps for physician analysis. Therefore, the proposed device and primary predicate are substantially equivalent in both intended use and Indications for Use.

Product Labeling:
Product labeling considerations are equivalent, providing comprehensive user guidance, Indications for Use, contraindications, warnings, and device operation instructions. Human factors usability testing confirms that users can safely and effectively operate the proposed vMap with provided instructions. The proposed and predicate (both primary and secondary) devices are prescription use-only devices, intended to be used by properly trained healthcare professionals. The product labeling information (Instructions for Use) for the proposed vMap, which is provided in the Labeling section of the eSTAR submission, provides adequate content to ensure that the proposed device can be used as intended, both safely and effectively, including Indications for Use and descriptions of the device components. Further, both the proposed and predicate devices' labeling include information regarding the maintenance and troubleshooting of the respective device. Therefore, the proposed device and predicate device are substantially equivalent with respect to the product labeling considerations.

Anatomical Sites:
The anatomical sites for electrophysiological data collection and cardiac mapping remain consistent between the proposed and

predicate (both primary and secondary) devices, utilizing non-invasive surface ECG collection at standard anatomical sites. Therefore, since the ECG inputs of the proposed device and predicate device are measured at the same surface anatomical sites and the devices' mapping outputs are directed towards the same intracardiac locations, the devices are substantially equivalent with respect to anatomical sites.

Patient Population:
Both the proposed and predicate (both primary and secondary) devices serve identical patient populations: adults undergoing EP procedures within clinical and hospital environments. Both devices can be used in clinical and hospital environments. Therefore, the proposed and predicate devices are substantially equivalent with respect to patient population.

Safety Characteristics:
Both the proposed vMap and its primary predicate are designed to assist in the mapping of potential arrhythmia sources per standard of care. The devices are not intended to take the place of medical training, clinical experience, and available clinical information (e.g., CT, MRI or other imaging information, patient history, disease characteristics, arrhythmia characteristics, anatomical mapping, voltage mapping), nor should the information provided by vMap be construed as definitive sources of, or targeting information for, arrhythmias. Notably, the proposed vMap does not necessitate patient-specific CT imaging, eliminating radiation exposure risk present in some competitor configurations. A comprehensive risk assessment has been performed on the proposed vMap device, and any potential risks have been identified and mitigated through performance testing and labeling. As such, the proposed and predicate devices are substantially equivalent with respect to safety characteristics.

Technological Characteristics:
Technological characteristics, including the principal mapping approach and analysis methodologies remain fundamentally similar. Specific changes such as hardware decoupling, 3D model manipulation, secure sandboxing, and automated cybersecurity features have been evaluated separately, as well as in aggregate, through performance testing and do not introduce different questions of safety or effectiveness.
Collectively, the results of the testing provided in this submission demonstrate that the differences between the proposed device and the predicate devices do not raise different questions of safety and effectiveness.

Conclusion:
The proposed vMap is substantially equivalent to the primary predicate device, vMap (K211546). Both devices have the same intended use and Indications for Use; to analyze non-invasive electrophysiological input to derive the associated cardiac signals to facilitate cardiac mapping. The devices have similar input data types and imaging functionalities. Vektor has performed comprehensive verification and validation activities to demonstrate that the vMap device meets all required specifications. The testing demonstrates that the technological differences between the proposed vMap and the predicate devices do not raise different questions of safety or effectiveness.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Vektor Medical, Inc. has conducted a summative usability study to evaluate vMap to support the safe and effective use of the Device for its intended user, uses, and use environment. A complete summative study was performed which supported FDA clearance of vMap under submission K211546. The recent study outlines the modifications made to the vMap and describes the usability testing methods used to evaluate the impact of these changes, ensuring that the current version of the product maintains acceptable safe usability performance. Both current study and the previous study were conducted in accordance with FDA's Guidance Document entitled, "Applying Human Factors and Usability Engineering to Medical Devices," issued February 3, 2016, and IEC 62366- 1:2015+AMD1:2020, Medical devices — Part 1: Application of usability engineering to medical devices.

Not Applicable. No clinical testing was conducted.

The usability testing evaluated the impact of the device changes (i.e., ECG streaming feature) and the results demonstrate that the current version of the product maintains acceptable usability performance.