November 9, 2021

Vektor Medical, Inc.
% Michael Billig
Co-Founder and Chief Executive Officer
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: K211546
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: May 18, 2021
Received: May 19, 2021

Dear Michael Billig:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211546

Device Name
Vektor Computational ECG Mapping System (vMap™)

Indications for Use *(Describe)*
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.

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 (K211546) (CONT.)

510(k) Notification K211546

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Carlsbad, CA, 92009
Phone: 800-610-8587

Sponsor Contact Person:

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Application Correspondent:

Michael J. Billig
Regulatory Consultant to Vektor Medical, Inc.
Co-Founder and Chief Executive Officer, Experien Group, LLC
Now a Part of Veranex
224 Airport Parkway, Suite 250
San Jose, CA, 95110

Date Prepared: November 8, 2021

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Vektor Computational ECG Mapping System (vMap™)

Generic/Common Name:

Electrophysiological cardiac mapping system

Classification:

21 CFR§870.1425, Programmable Diagnostic Computer, Class II

Product Code:

DQK, Computer, Diagnostic, Programmable

510(k) SUMMARY (K211546) (CONT.)

PREDICATE DEVICE(S) [807.92(a)(3)]

Primary Predicate Device: Volta Medical VX1 (K201298)

Secondary Predicate Device: Medtronic, Inc. CardioInsight® Cardiac Mapping System (K181918)

DEVICE DESCRIPTION [807.92(a)(4)]

The Vektor Computational ECG Mapping System (vMap™) is a non-invasive software-driven tool for beat-by-beat, multi-chamber, two-dimensional ("2D") and three-dimensional ("3D") analysis and mapping of the heart. vMap™ analyzes standard, 12-lead electrocardiographic signals acquired non-invasively from the body surface. vMap™ uses this data to provide various 2D cardiac information and interactive 3D color maps, including cardiac electrical features for analysis by a physician. vMap™ can be used in the clinical environment, such as the electrophysiology ("EP") lab, and in a hospital environment.

The vMap™ System consists of three key components:

1. The vMap™ Software, which drives vMap™ and its core analysis functionalities;
2. The vMap™ Hardware, the computer workstation which facilitates the use of the vMap™ Software; and
3. The vMap™ Disposables, which includes a "Mapping Key" that serves as a license mechanism for the software. Commercial off-the-shelf components such as a USB flash drive and a set of FDA-cleared ECG leads are provided for the physician's convenience.

The electrocardiogram (ECG) signals are displayed and used in proprietary algorithms to transform the measured body surface signals into cardiac signals. vMap™ provides information directly to the physician to help assess patients exhibiting abnormal heart rhythms (arrhythmias). vMap™ provides this information by analyzing electrocardiographic information with reference to an arrhythmia-specific cardiac voltage library.

INDICATIONS FOR USE [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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

The proposed device and the predicate devices have the same intended use and similar Indications for Use. All devices are non-invasive cardiac mapping systems for use by licensed physicians on patients undergoing electrophysiology ("EP") procedures. vMap™, VX1, and CardioInsight® all perform analysis, display, and storage of EP data and maps for analysis by a physician.

The proposed and predicate devices share key technological similarities. In order to process the device signal input and provide output, all devices analyze cardiac electrogram data in order to generate electrical activity "maps" indicative of cardiac electrical activity within the heart anatomy for physician analysis. In consideration of the specific analysis methodology, vMap™

510(k) SUMMARY (K211546) (CONT.)

and CardioInsight utilize electrical activity information gathered from surface-lead inputs to estimate the origins of the measured electrical activity. In this analysis, both devices consider the patient's cardiac anatomy to arrive at the mapping result. Further, vMap™ and VX1 also leverage analytical parameters from externally developed models as part of the analysis to relate the input source signals to the final geometric output. There are a few differences between the proposed device and the predicate devices which relate primarily to input signals, mathematical approach, and output map formats, which do not raise different questions of safety or effectiveness, as was further confirmed through the results of bench, usability, and clinical performance testing.

Table 1 presents a tabular comparison of technological characteristics between the proposed device and predicate devices.

510(k) SUMMARY (K211546) (CONT.)

Table 1: Substantial Equivalence Table

Feature	**Proposed Device** **Vektor Medical, Inc. – Vektor Computational ECG Mapping System (vMap™) (K211546)**	**Primary Predicate Device** **Volta Medical – VX1 (K201298)**	**Secondary Predicate Device** **Medtronic Inc. – CardioInsight® Cardiac Mapping System (K181918)**
Classification	21 CFR§870.1425, Programmable Diagnostic Computer	21 CFR§870.1425, Programmable Diagnostic Computer	21 CFR§870.1425, Programmable Diagnostic Computer
Product Code	DQK, Computer, Diagnostic, Programmable	DQK, Computer, Diagnostic, Programmable	DQK, Computer, Diagnostic, Programmable
Intended Use/Indications for Use			
Indications for Use	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.	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 CardioInsight Cardiac Mapping System is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.
Intended Use Population	Individuals undergoing EP procedures	Individuals undergoing EP procedures	Individual undergoing EP procedure
Intended Use Environment	Clinical and hospital environment	Clinical and hospital environments	Clinical and hospital environment
Prescription/Over-the-Counter	Rx	Rx	Rx

510(k) SUMMARY (K211546)

Table 1: Substantial Equivalence Table (cont.)

Feature		**Proposed Device** **Vektor Medical, Inc. – Vektor Computational ECG Mapping System (vMap™) (K211546)**	**Primary Predicate Device** **Volta Medical – VX1 (K201298)**	**Secondary Predicate Device** **Medtronic Inc. – CardioInsight® Cardiac Mapping System (K181918)**
Technological Characteristics				
Mapping Display	Principal Mapping Approach	Displays 3D anatomical maps after analyzing surface electrograms and patient phenotype using signal processing and computational modeling techniques.	Displays adjudications as visual cues after analyzing intra-cardiac atrial electrograms in real-time using signal processing, and deep and machine learning techniques.	Displays 3D anatomical maps after analyzing surface electrograms and imaging information using signal processing techniques.
	Cardiac Model Used	Standard, idealized model	N/A; the locations are displayed relative to the mapping catheter electrodes.	Individualized, patient-specific model based on segmented CT image
	Cardiac Maps Provided	3D Activation Heatmap: • Individual-beat • Composite beat • Beat-averaged summary • Custom Beat	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.	3D Electroanatomical Maps: • Phase Map • Potential Map • Voltage Map • Activation Maps (Activation Time, Directional Activation, Slew Rate, Propagation)
Principles of Operation	Software-Driven Analysis	Yes	Yes	Yes
	Display	• 2D electrogram signals display • Beat-by-beat comparison "mosaic" display • 3D beat and composite maps	• 2D electrogram signals display • Dispersion Location • Mapping Catheter • Estimated Reference Cycle Length • Mapping Cycle Length	• 2D electrogram signals display • "Premature Beats" filter • 3D beat and composite maps
	Reports of Diagnostic Results	No	No	No
	Electrophysiological Input	Patient-specific surface ECG (12-lead, acquired by compatible and cleared ECG devices)	Patient-specific intracardiac electrogram information (acquired by compatible catheter)	Patient-specific surface ECG (proprietary, acquired by device vest)

510(k) SUMMARY (K211546)

Table 1: Substantial Equivalence Table (cont.)

Feature		Proposed Device Vektor Medical, Inc. – Vektor Computational ECG Mapping System (vMap™) (K211546)	Primary Predicate Device Volta Medical – VX1 (K201298)	Secondary Predicate Device Medtronic Inc. – CardioInsight® Cardiac Mapping System (K181918)
	Considers Disease Phenotype	Yes, through end user input and pre-computed cardiac voltage library.	Disease phenotype information is reflected within mapping catheter readings. The deep learning model within the device was developed using electrograms recorded across a representative range of clinical disease phenotypes, such that the algorithm can be generalized accordingly.	Yes, through CT scans.
	Mathematical Methodology	The system leverages a pre-computed cardiac voltage library which uses forward models and mathematical algorithms to derive cardiac signals from body surface signals.	The device leverages a machine learning/deep learning algorithm that includes analytical parameters that pertain to previous similar procedures to analyze electrograms and identify the associated mapping outputs (locations associated with dispersion/fractionation).	The system uses the inverse solution and mathematical algorithms to transform the measured body surface signals into cardiac signals.
	Method for Establishing Analytical Parameters	RhythmMatrix – a collection of over one million precomputed cardiac voltage library solutions. Each pre-computed solution includes a simulated cardiac activation source location and its corresponding vectorcardiogram.	The training set of the deep learning algorithm consists of a "very large database of 1.5 second snippets of multipolar intra-cardiac atrial electrograms."	Mathematical-based inverse analysis is based on individual patient information only.
System Components		• Computer Workstation (monitor, main control unit, peripherals, and cords) • Software/Firmware/Algorithm • Off-the-shelf (OTS) ECG (not provided) and ECG electrodes (12-Lead) (optional)	• Computer Workstation • Software/Firmware/Algorithm • Off-the-shelf (OTS) mapping catheters (not provided).	• Computer Workstation (monitor, core processor/isolation transformer, peripherals, and cabling) and Cart • Software/Firmware/Algorithm • Vest with Sensor Array

510(k) SUMMARY (K211546)

Table 1: Substantial Equivalence Table (cont.)

Feature	**Proposed Device** **Vektor Medical, Inc. – Vektor Computational ECG Mapping System (vMap™) (K211546)**	**Primary Predicate Device** **Volta Medical – VX1 (K201298)**	**Secondary Predicate Device** **Medtronic Inc. – CardioInsight® Cardiac Mapping System (K181918)**
Operational Workflow	• Creates patient records • Acquires ECG input (from FDA-cleared ECG acquisition devices) • Analyzes electrocardiographic signals • Creates and reviews maps	• Creates patient records • Acquires electrogram input (from compatible FDA-cleared mapping catheters) • Analyzes electrocardiographic signals and derives mapping outputs for real-time review	• Creates patient records • Segments heart and vest electrodes • Analyzes electrocardiographic signals • Creates and reviews maps

510(k) SUMMARY (CONT.)

PERFORMANCE DATA [807.92(b)]

All necessary bench, usability, and clinical testing were conducted on vMap™ to support a determination of substantial equivalence to the predicate device.

[807.92(b)(1)] Nonclinical Testing Summary:

The nonclinical, bench testing included:

- Shipping and packaging validation, in accordance with ISTA 3A:2018, *Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less.*
- Electrical safety and electromagnetic compatibility testing in accordance with the applicable IEC 60601 series consensus standards as well as the recommendations of FDA's Guidance Document entitled, "*Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices,"* issued July 11, 2016.
- Software verification and validation completed in alignment with FDA Guidance Document entitled, "*General Principles of Software Validation*," issued January 11, 2002.
- Documentation, verification, validation, and uncertainty quantification of the Device's arrhythmia-specific cardiac voltage libraries in accordance with FDA's Guidance Document entitled, "*Reporting of Computational Modeling Studies in Medical Device Submissions*," issued September 21, 2016.
- Human factors usability testing, conducted in accordance with FDA's Guidance Document entitled, "*Applying Human Factors and Usability Engineering to Medical Devices*," issued February 03, 2016 and IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*.

The collective results of bench and usability testing, in conjunction with the multi-center clinical study of vMap™, demonstrate that the proposed device meets all design specifications and performs as intended for its intended use.

[807.92(b)(2)] Clinical Testing Summary:

A retrospective, blinded, and multi-center clinical study was conducted to validate performance of vMap™. The outcomes of this clinical study validated the performance of vMap™ by confirming that the Device, when used by the intended user in the intended use patient population, was able to provide information accurately across all nine supported arrhythmia and pacing types and in patients with and without structural heart disease. The results support that the vMap™ output substantiates vMap™'s intended use/Indications for Use for "the analysis, display, and storage of cardiac electrophysiological data and maps for analysis by a physician."

Four investigational sites within the United States were identified and selected based on qualifying criteria. Across these four sites, the study retrospectively enrolled 225 patients associated with 255 arrhythmia/pacing episodes. Of the 225 subjects, 61.3% of the subjects were male, with a representative range of ages. The study subjects were representative of the intended user patient population, and the ECG episodes collected included all arrhythmia/pacing subtypes supported by vMap™.

510(k) SUMMARY (CONT.)

The study results demonstrated acceptable clinical accuracy performance of vMap™. The **primary endpoint** of the study was achieved. Of 75 episodes, which met the criteria for inclusion in this analysis, (premature ventricular complex (PVC) and ventricular tachycardia (VT) arrhythmias in cases with structurally normal hearts and less than 10% scar), vMap™ correctly identified chamber/region of the clinical arrhythmia ("CAT") location as determined by ground truth in 74 episodes, representing an accuracy of 98.7% (96.0 - 100%).

In addition, both key **secondary endpoints** were achieved, as follows:

1. Of 255 total episodes, vMap™ correctly identified the chamber/region of the CAT location as determined by ground truth (Atria: left atrial free wall, septum, or right atrial free wall; Ventricles: left ventricular free wall, septum, or right ventricular free wall) with an accuracy of 96.9% (95.1% - 98.7%) across all nine arrhythmia subtypes supported by vMap™.
2. Of 255 total episodes, vMap™ correctly identified the segment or neighboring segment of the CAT location as determined by ground truth with an accuracy of 97.3% (95.2% - 99.3%) across all nine arrhythmia subtypes supported by vMap™.

CONCLUSIONS [807.92(b)(3)]

The proposed device and the predicate devices have the same intended use and similar Indications for Use. Furthermore, the proposed and predicate devices share key technological similarities. Demonstrated by the results of bench, usability, and clinical testing, the design of which were highly similar to that of the predicate devices, any technological differences presented with the proposed device do not raise different questions of safety or effectiveness, and the proposed device is as safe and as effective as the predicate devices for the same intended use.

SUMMARY

The predicate device's Indications for Use is substantially equivalent to the proposed Indications for Use for vMap™. Any differences in the technological characteristics between the devices do not raise different questions of safety or effectiveness. Thus, the Vektor Computational ECG Mapping System (vMap™) is substantially equivalent to the predicate devices, the Volta Medical VX1 (K201298) and the Medtronic, Inc. CardioInsight® Cardiac Mapping System (K181918).