January 21, 2023

Volta Medical
℅ Kristin Zielinski Duggan
Partner
Hogan Lovells US LLP
555 13 Street NW
Washington, District of Columbia 20004

Re: K223516
Trade/Device Name: VX1+
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: November 22, 2022
Received: November 22, 2022

Dear Kristin Zielinski Duggan:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223516

Device Name
VX1+

Indications for Use *(Describe)*
The VX1+ assists operators in the real-time manual or automatic 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.

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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510(k) SUMMARY

VOLTA MEDICAL's VX1+

Submitter

Volta Medical

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France

Phone: +33 7 68 02 54 99

Contact Person: Paola MILPIED

Date Prepared: November 22, 2022

Name of Device: VX1+

Common or Usual Name: Cardiac Mapping System

Classification Name: Programmable Diagnostic Computer

Regulatory Class: 21 C.F.R § 870.1425

Product Code: DQK

Predicate Devices

Volta Medical, VX1 (K201298)

Device Description

The VX1+ is a machine and deep learning based-algorithm designed to assist operators in the real-time manual or automatic annotation of 3D anatomical and electrical maps of the human heart for the presence of electrograms exhibiting spatio-temporal dispersion, i.e., dispersed electrograms (DEs).

The VX1+ device is a non-sterile reusable medical device, composed of a computing platform and a software application. VX1+ works with all existing 510(k)-cleared catheters that meet specific dimension requirements and with one of the three specific data acquisition systems:

- two compatible EP recording systems (identical to VX1 (Volta Medical (K201298)): the *LabSystem Pro* EP Recording System (Boston Scientific) (K141185) or the *MacLab CardioLab* EP Recording System (General Electric) (K130626),
- a 3D mapping system (novelty compared to VX1): *EnSite X* 3D mapping system (Abbott) (K221213).

A connection cable is used to connect the corresponding data acquisition system to the VX1+ system, depending on the type of communication used:

- Unidirectional analog communication with the EP recording systems via a custom-made cable (two different variants: *DSUB, Octopus*) and an Advantech PCI-1713U analog-to-digital converter, which acquires analog data, digitizes it, and transmits the digital signals to the computer that hosts the VX1+ software.
- Bidirectional digital communication with the EnSite 3D mapping system via an ethernet cable (four different lengths: 20,10, 5 or 2m) which transmits the digital signals directly to the computer.

The computer and its attached display are located outside the sterile operating room area. The VX1+ software analyzes the patient's electrograms to cue operators in real-time to intra-cardiac electrograms of interest for atrial regions harboring DEs as well as a cycle length estimation from electrograms recorded with the mapping and the coronary sinus catheters. The results of the analysis are graphically presented on the attached computer display and/or on a secondary medical screen or on an operating room widescreen. The identified regions of interest are either manually (all configurations) or automatically (only available in digital bidirectional communication with the EnSite X 3D mapping system) tagged in the corresponding 3D mapping system.

Intended Use / Indications for Use

The VX1+ assists operators in the real-time manual or automatic 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.

Summary of Technological Characteristics

The VX1+ device is a new device manufactured by Volta Medical, based on the same concept (identification of electrograms dispersion) than predicate VX1.

VX1 and VX1+ are both software programs that work with standard electrophysiology catheters to aid in mapping the heart. Both devices aid operators by assisting in annotating complex electrical maps of the heart, and both devices process and output information via a computer and display that are operated by use of a keyboard / mouse. VX1 and VX1+ have the same input (intra-cardiac multipolar signals) and the same output (associated dispersion), with the addition of the 3D position of the corresponding electrodes available in VX1+.

VX1 and VX1+ support Electrophysiologists in the manual annotation of dispersed areas using a unidirectional analog communication. In addition, VX1+ brings the ability to connect to a

specific 3D mapping system through a bidirectional digital communication, which enables the operator to use the automatic tagging function.

The VX1+ indications for use are the same as for the VX1, with the addition of automatic annotation. The VX1+ displays an analysis of dispersed electrograms, just as VX1 and therefore, the intended use of the VX1+ and the VX1 are essentially the same.

	Volta Medical VX1+	**Volta Medical VX1 (K201298)**
Regulation	21 C.F.R. § 870.1425	21 C.F.R. § 870.1425
Classification Name	Programmable Diagnostic Computer	Programmable Diagnostic Computer
Product Code	DQK	DQK
Indications for Use	The VX1+ assists operators in the real-time manual or automatic 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 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.
System Type	Signal processing based atrial mapping system	Signal processing based atrial mapping system
Primary Feature	Displays and analyzes electrical maps such as intra-cardiac electrograms in real-time using machine learning and signal processing techniques	Displays and analyzes electrical maps such as intra-cardiac electrograms in real-time using machine learning and signal processing techniques

	Volta Medical VX1+	Volta Medical VX1 (K201298)
3D Location Technology	Electroanatomic location is performed by another commercially available navigation system. In bidirectional digital communication, 3D Location is shared by the 3D Mapping System with VX1+.	Electroanatomic location is performed by another commercially available navigation system.
Compatible Acquisition Systems	• LabSystem Pro EP Recording System (Boston Scientific) • CardioLab EP Recording System (GE) • EnSite X 3D Mapping System (Abbott)	• LabSystem Pro EP Recording System (Boston Scientific) • CardioLab EP Recording System (GE)
Compatible Catheters	Any compatible mapping and ablation catheter	Any compatible mapping and ablation catheter
Display(s)	Color monitor	Color monitor
Multi-Display Support	Yes, duplicate display on a secondary medical screen or on an operating room widescreen	Yes, duplicate display on a secondary medical screen or on an operating room widescreen
Control	Standard keyboard / mouse	Standard keyboard / mouse
Display Timing	Real-time	Real-time
Inputs Required	Analog or digital Intra-cardiac signals In digital mode, 3D locations of corresponding electrodes bipoles	Analog Intra-cardiac signals
Output	Presence or absence of electrogram dispersion at each electrode bipole under consideration In digital mode, 3D locations of corresponding electrodes bipoles Computed values of mapping and reference cycle length	Presence or absence of electrogram dispersion at each electrode bipole under consideration Computed values of mapping and reference cycle length
Duration of Electrogram Recordings	1.5 Seconds	1.5 Seconds
Ouput Display	The system generates color coded symbol(s) that indicates to the operator that the area under	The system generates color coded symbol(s) that indicates to the operator that the area under

	Volta Medical VX1+	Volta Medical VX1 (K201298)
	investigation is one exhibiting dispersion In bidirectional digital communication, validated dispersion area can also be automatically displayed in the 3D mapping system as tags in the 3D atrial shell	investigation is one exhibiting dispersion
Signal Information Displayed	Acquired patient signals, including body surface ECG and intra-cardiac EGMs.	Acquired patient signals, including body surface ECG and intra-cardiac EGMs.
Computing Platform	Computer with Intel Core i7-7700 CPU (8MB Cache, up to 4.20 GHz, RAM 32 GB), with integrated analog/digital converter PCI card and TPM (Trusted Platform Module) Debian-based Linux OS	Computer with Intel Core i5-6500 CPU (6MB Cache, up to 3.60 GHz, RAM 32 GB), with integrated analog/digital converter PCI card Windows 10 or higher OS
Hardware Design and Materials	Computing platform, proprietary software algorithm, monitor, mouse/keyboard, custom-made analog connection cable, ethernet cable, acquisition system	Computing platform, proprietary software algorithm, monitor, mouse/keyboard, custom-made analog connection cable, acquisition system

Performance Data – Nonclinical Tests:

The Volta Medical VX1+ was subjected to non-clinical testing including electromagnetic compatibility and electrical safety tests, rigorous software verification and validation testing including unitary testing of the main algorithm modules of VX1+ application. Specifically the *Reader Study* described in VX1's 510(k) (K201298) and intended to show that the algorithm's adjudications acceptably correlate with unlimited-time expert visual analysis, was replayed with VX1+ dispersion algorithm.

A usability verification and validation study was launched in a simulated environment at Volta Medical headquarters and in a clinical environment in the scope of the AMPERE study. Usability evaluation did not raise any safety issues and confirmed the relevance of the related risks identified.

Performance Data – Clinical Tests:

Since a full set of tests was performed, including a non-regression analysis of VX1+ versus VX1 with respect to dispersion adjudication, additional clinical data is not required to demonstrate substantial equivalence of the VX1+. However; for completeness, the Company supplied data from an OUS clinical study of the VX1+. The study was aimed at evaluating the reliability of VX1+ detection of dispersed electrograms and automatic tagging function, and involved 1 center, 4 operators, and 22 patients. The results indicate that VX1+ reliably assists operators in the detection and auto-tagging of regions harboring dispersed electrograms during AF/AT, with no associated additional risks or procedure time.

Conclusions

The VX1+ is as safe and effective as the VX1. The VX1+ has the same intended uses and same indications, and substantially similar technological characteristics, and principles of operation as its predicate device. The introduction of the automatic tagging feature does not alter the intended use of the device as an electrophysiological evaluation tool and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences (i.e., bidirectional communication with the acquisition system) between the VX1+ and its predicate device raise no new issues of safety or effectiveness. Performance data, as described above, demonstrate that the VX1+ device is as safe and effective as the VX1. Thus, the VX1+ device is substantially equivalent.