September 27, 2023

Volta Medical
℅ Kristin Duggan
Partner
Hogan Lovells US LPP
555 13th St. NW
Washington, District of Columbia 20004

Re: K232616
Trade/Device Name: Volta AF-Xplorer
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: August 28, 2023
Received: August 28, 2023

Dear Kristin 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 (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.

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,

for Hetal B. Odobasic -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 Statement

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 on last page

510(k) Number *(if known)*

K232616

Device Name

Volta AF-Xplorer

Indications for Use *(Describe)*

The Volta AF-Xplorer 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 Volta AF-Xplorer 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

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

VOLTA MEDICAL's Volta AF-Xplorer

Submitter

Volta Medical
65 Avenue Jules Cantini
13006 Marseille
France

Phone: +33 7 68 02 54 99
Contact Person: Paola MILPIED

Date Prepared: August 28, 2023

Name of Device: Volta AF-Xplorer

Common or Usual Name: Cardiac Mapping System

Classification Name: Programmable Diagnostic Computer

Regulatory Class: 21 C.F.R § 870.1425

Product Code: DQK

Primary Predicate Device

Volta Medical, VX1+ (K223516)

Predicate Device

Volta Medical, VX1 (K201298)

Purpose of the Special 510(k) notice

The Volta AF-Xplorer is a modification to the VX1+ (K223516) device which incorporates the pre-processing from the VX1 (K201298).

Intended Use / Indications for Use

The Volta AF-Xplorer 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 Volta AF-Xplorer 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 Volta AF-Xplorer 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.

The Volta AF-Xplorer device is a non-sterile reusable medical device, composed of a computing platform and a software application. Volta AF-Xplorer 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 and VX1+ (Volta Medical (K201298, K223516)): the *LabSystem Pro* EP Recording System (Boston Scientific) (K141185) or the *MacLab CardioLab* EP Recording System (General Electric) (K130626),

- a 3D mapping system (new compared to VX1 and identical to VX1+): *EnSite X* 3D mapping system (Abbott) (K221213).

A connection cable is used to connect the corresponding data acquisition system to the Volta AF-Xplorer system, depending on the type of communication used:

- Unidirectional analog communication with the EP recording systems via a custom-made cable (two diferent 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 Volta AF-Xplorer 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 Volta AF-Xplorer software analyzes the patient's electrograms to cue operators in real-time to intra-cardiac electrograms of interest for atrial regions harboring dispersed electrograms 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.

Technological Characteristics

The Volta AF-Xplorer device is a modified device manufactured by Volta Medical, based on the same concept (identification of electrograms dispersion) than predicates VX1+ and VX1.

Volta AF-Xplorer, VX1+ and VX1 are software programs that work with standard electrophysiology catheters to aid in mapping the heart. All three devices aid operators by assisting in annotating complex electrical maps of the heart, and process and output information via a computer and display that are operated by use of a keyboard / mouse. Volta AF-Xplorer, 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 Volta AF-Xplorer and VX1+.

Volta AF-Xplorer, VX1+ and VX1 support Electrophysiologists in the manual annotation of dispersed areas using a unidirectional analog communication. Both Volta AF-Xplorer and VX1+ have 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 Volta AF-Xplorer indications for use are identical to the VX1+ and the VX1. The Volta AF-Xplorer displays an analysis of dispersed electrograms, just as VX1+ and VX1 and therefore, the intended use of the Volta AF-Xplorer and the VX1+ and the VX1 are identical.

	Volta Medical Volta AF-Xplorer (subject)	Volta Medical VX1+ (K223516)	Volta Medical VX1 (K201298)
Regulation	21 C.F.R. § 870.1425	21 C.F.R. § 870.1425	21 C.F.R. § 870.1425
Classification Name	Programmable Diagnostic Computer	Programmable Diagnostic Computer	Programmable Diagnostic Computer
Product Code	DQK	DQK	DQK
Indications for Use	The Volta AF-Xplorer 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 Volta AF-Xplorer 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 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	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	Displays and analyzes electrical maps such as intra-cardiac electrograms in real-time using machine learning and signal processing techniques

	Volta Medical Volta AF-Xplorer (subject)	Volta Medical VX1+ (K223516)	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 Volta AF-Xplorer.	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) • 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	Any compatible mapping and ablation catheter
Display(s)	Color monitor	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	Yes, duplicate display on a secondary medical screen or on an operating room widescreen
Control	Standard keyboard / mouse	Standard keyboard / mouse	Standard keyboard / mouse
Display Timing	Real-time	Real-time	Real-time
Inputs Required	Analog or digital Intra-cardiac signals In digital mode, 3D locations of corresponding electrodes bipoles	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	Presence or absence of electrogram dispersion at each electrode bipole under consideration	Presence or absence of electrogram dispersion at each electrode bipole under consideration

	Volta Medical Volta AF-Xplorer (subject)	Volta Medical VX1+ (K223516)	Volta Medical VX1 (K201298)
	Computed values of mapping and reference cycle length	In digital mode, 3D locations of corresponding electrodes bipoles Computed values of mapping and reference cycle length	Computed values of mapping and reference cycle length
Duration of Electrogram Recordings	1.5 Seconds	1.5 Seconds	1.5 Seconds
Ouput Display	The system generates color coded symbol(s) that indicates to the operator that the area under 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	The system generates color coded symbol(s) that indicates to the operator that the area under 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	The system generates color coded symbol(s) that indicates to the operator that the area under 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.	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 **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

	Volta Medical Volta AF-Xplorer (subject)	Volta Medical VX1+ (K223516)	Volta Medical VX1 (K201298)
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, ethernet cable, acquisition system	Computing platform, proprietary software algorithm, monitor, mouse/keyboard, custom-made analog connection cable, acquisition system

The hardware and software differences to the subject device do not introduce new questions of safety or effectiveness.

Performance Data

Software design verification was performed on the subject Volta AF-Xplorer device with the software that included the same pre-processing as cleared in VX1 and the same post-processing specifications as cleared in VX1+. The testing and acceptance criteria are the same as those in the predicate VX1+ and VX1 devices. Bench testing was previously conducted in the VX1+ (K223516) and VX1 (K201298) to demonstrate rigorous software verification and validation testing including unitary testing of the main algorithm modules. The processing was evaluated and demonstrated equivalent performance with the acceptance criteria from the VX1+ and VX1 studies.

Conclusions

The Volta AF-Xplorer is as safe and effective as the VX1+ and the VX1. The Volta AF-Xplorer has the same intended uses and same indications, and substantially similar technological characteristics, and principles of operation as its predicate devices VX1+ and VX1. The modification to the same pre-processing specification as cleared in VX1 and the same post-processing specifications as cleared in VX1+ 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. Performance data, as described above, demonstrate that the Volta AF-Xplorer device is as safe and effective as the VX1+ and the VX1. Thus, the Volta AF-Xplorer device is substantially equivalent.