



September 16, 2020

Volta Medical
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: K201298
Trade/Device Name: VX1
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: August 17, 2020
Received: August 17, 2020

Dear Janice Hogan:

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,

Mark Fellman
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

510(k) Number (if known)

K201298

Device Name

VX1

Indications for Use (Describe)

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.

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
K201298

Submitter

Volta Medical
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Contact Person: Théophile Mohr Durdez

Date Prepared: September 15, 2020

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: Biosense Webster, Inc.'s CARTO® XP V10 System (K093566)

Device Description:

The VX1™ is a machine and deep learning based-algorithm designed to assist operators in the real-time manual annotation of 3D anatomical and electrical maps of the human atria for the presence of electrograms exhibiting spatiotemporal dispersion during atrial fibrillation or atrial tachycardia", i.e., dispersed intra-cardiac atrial electrograms (DEs). The device works with all existing 510(k) cleared catheters that meet specific dimension requirements and with two data acquisition systems: the *LabSystem Pro* Acquisition System (Boston Scientific) (K141185) and the *MacLab CardioLab* Acquisition System (General Electric) (K130626). 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. 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.

Intended Use / Indications for Use:

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.

Summary of Technological Characteristics Compared to the Predicate Device:

The VX1 device and its predicate (the CARTO[®] XP V10 System; K093566) both work with standard electrophysiology catheters to aid in mapping the atria. The predicate device contains several functional modules that are not included in the VX1 device; however, as described in the table below, these functions can generally be performed by another (compatible) device that can be used during the same procedure that includes the VX1 device. Whether these functions are bundled in one device (as with the predicate device) or performed by separate devices during the same procedure does not affect the subject device performance nor raise different questions of safety or effectiveness. Because mapping can be used independently, the provision of a separate functionality in the VX1 versus an integrated functionality in the predicate does not raise new types of questions or otherwise adversely impact performance, as confirmed in the submitted testing.

In particular, the VX1 performs an equivalent function to the CFAE Module of the predicate device. Both devices aid operators by assisting in annotating complex electrical maps of the atria, and both devices process and output information via a computer and display that are operated by use of a keyboard / mouse. Additionally, the signals identified by the VX1 device are of the same nature (multipolar atrial electrograms) as those identified by the CFAE module of CARTO, as demonstrated in the definition of dispersion which partly relies on the definition of CFAE. Both devices also have the same input (intra-cardiac signals) and output (associated dispersion / fractionation).

The CARTO CFAE module; however, performs analysis of *individual* per-procedural data sets, whereas VX1 includes analytical parameters that pertain to previous similar procedures. Specifically, VX1 methods rely on conceptualizing a discriminant algorithm, which, during training, drew on anonymized information from a very large database of 1.5 second snippets of multipolar intra-cardiac atrial electrograms located on a dedicated data server. In actual commercial use, however, the trained machine and deep learning models are incorporated into the stand alone local software application which is not connected to a network.

Like the predicate device, the VX1 assists in the real-time annotation of complex 3D anatomical and electrical maps of the human atria, including the presence of multipolar electrograms. Thus, both the subject and predicate device have the same intended use.

The indications for use of the CARTO[®] XP V10 System, while broader, specify that it “displays Complex Fractionated Atrial Electrograms (CFAE).” Spatiotemporal dispersed Intra-cardiac atrial electrograms are a non-exclusive subset of CFAEs in which the

fractionation occurs in a non-simultaneous fashion at neighboring electrode locations (temporal dispersion) and are organized in well-defined clusters (spatial dispersion). Thus, the predicate CFAE technology relates to the same cardiac phenomena for which the VX1 is indicated for use.

Neither device is intended for directing treatment or affecting the outcome of any particular heart arrhythmia.

The difference in indications therefore does not alter the intended diagnostic effect, and therefore the first criterion for a finding of substantial equivalence is satisfied.

	Volta Medical VX1	CARTO® XP System with CARTOPRESS™ Module (V10) K093566	Comments
Regulation	21 C.F.R. § 870.1425 Programmable Diagnostic Computer Product Code: DQK	21 C.F.R. § 870.1425 Programmable Diagnostic Computer Product Code: DQK	Same
Indications for Use	<p>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.</p> <p>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.</p>	<p>The intended use of the CARTO® XP System with CARTOPRESS™ Module (V10) is catheter-based atrial and ventricular mapping.</p> <p>The CARTO® XP System with CARTOPRESS™ Module (V10) allows real-time display of cardiac maps in a number of different formats. Maps may be displayed as cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, impedance maps, and cardiac chamber geometry maps. The acquired patient signals, including body surface EGG and intra-cardiac electrograms may also be displayed in real-time on the system display screen.</p> <p>CARTO® XP System with CARTOPRESS™ Module (V10) includes the CARTOMERGE® capability to import, register, and</p>	<p>Like the predicate device, the VX1 assists in the real-time annotation of complex 3D anatomical and electrical maps of the human atria, including the presence of multipolar electrograms. Thus, both the subject and predicate device have the same intended use.</p> <p>The indications for use of the CARTO® XP V10 System, while broader, specify that it “displays Complex Fractionated Atrial Electrograms (CFAE).” Spatiotemporal dispersed intra-cardiac atrial electrograms are a non-exclusive subset of CFAEs in which the fractionation occurs in a non-simultaneous fashion at neighboring electrode locations (temporal dispersion) and are organized in well-defined clusters (spatial dispersion). Thus, the predicate CFAE technology relates to the same cardiac</p>

	Volta Medical VX1	CARTO® XP System with CARTOPRESS™ Module (V10) K093566	Comments
		<p>merge CT or MRI structural images with CARTO Maps physiological information and real-time catheter navigation. CARTO® XP System with CARTOPRESS™ Module (V10) also allows the integration of intra-cardiac echo (ICE) 2D images to provide 3D combined maps.</p> <p>CARTO® XP System with CARTOPRESS™ Module (V10) includes Fast Anatomical Mapping (FAM) that is a method for quick creation of cardiac anatomical volumes using catheters with magnetic location sensors, supports the LASSO® NAV Catheter with location sensors, displays Complex Fractionated Atrial Electrograms (CFAE), and adds Pace-Mapping Software (PaSo) ECG signal correlation tool.</p>	<p>phenomena for which the VX1 is indicated for use.</p> <p>Neither device is intended for directing treatment or affecting the outcome of any particular heart arrhythmia.</p> <p>Additional CARTO® XP System with CARTOPRESS™ Module (V10) functions can be accomplished by other (compatible) devices used in the same procedure as the VX1.</p> <p>Thus, the difference in indications does not alter the intended diagnostic effect.</p>
System Type	Signal processing-based atrial mapping system.	Electromagnetic and catheter-based atrial and ventricular mapping system.	Similar catheter-based systems. The lack of ventricular mapping in the subject device does not affect its performance relative to its atrial mapping functionality. Further, use of the VX1 does not preclude the use of other mapping systems during the same procedure which can perform broad mapping features (e.g., ventricular mapping). The VX1 simply provides complementary additional information regarding dispersed intra-cardiac atrial electrograms to the user in addition to the

	Volta Medical VX1	CARTO® XP System with CARTOPRESS™ Module (V10) K093566	Comments
			information provided by traditional mapping systems. Thus, there are no different questions of safety or effectiveness raised by the VX1 system.
Display(s)	Color monitor	Color monitor	Same
Control	Standard keyboard / mouse	Standard keyboard / mouse	Same
Inputs Required	Intra-cardiac atrial electrograms that are recorded with catheters, amplified and redirected to an acquisition system on which they are displayed.	ECG and electrogram data from the patient captured with proprietary and non-proprietary catheters and patches.	<p>Comparable inputs to those captured by the CARTO XP System (e.g., ECG and EGM data) can be captured by compatible devices used during the same procedure that includes VX1.</p> <p>Whether these functions are bundled in one device (as with the predicate device) or performed by separate devices during the same procedure does not affect the subject device performance nor raise different questions of safety or effectiveness. Use of the VX1 does not preclude the use of other mapping systems during the same procedure which can provide appropriate input (ECG and patches).</p>
Principal Mapping Output	Displays adjudications as visual cues after analyzing intra-cardiac atrial electrograms in real-time using signal processing techniques.	Displays anatomical and electrical maps such as activation and voltage maps of the human heart in real-time using magnetic navigation techniques and ECG-EGM analysis.	Use of the VX1 does not preclude the use of other mapping systems during the same procedure which can perform these additional mapping features. Thus, there is no effect on safety or effectiveness.
Map Types Generated	Real-time Dispersed Electrogram (DE) subtype of multipolar electrogram map- The operator is provided with display of the	Real-time 3D cardiac maps including: cardiac electrical activation maps, cardiac electrical propagation maps, impedance maps, and	VX1 provides real-time adjudications of dispersion without providing corresponding 3D mapping information. The use of the VX1 does not preclude the

	Volta Medical VX1	CARTO® XP System with CARTOPRESS™ Module (V10) K093566	Comments
	electrode locations where dispersed or non-dispersed electrograms have been recorded during atrial fibrillation or atrial tachycardia.	cardiac chamber geometry maps. Complex Fractionated Atrial Electrograms (CFAE) are displayed on maps that are colored according to the duration and repetitions of fragmented electrograms.	use of other mapping systems during the same procedure which can perform 3D cardiac maps including: cardiac electrical activation maps, cardiac electrical propagation maps, impedance maps, and cardiac chamber geometry maps.
Compatible Catheters	Any compatible catheter meeting the requirements listed below: <u>Compatibility Requirements:</u> Mapping catheter: - Electrode size : 1 mm - Inter-electrode Spacing : 2 – 3 mm - Number of selected dipoles : 10 Coronary sinus catheter: - Electrode size: 1 mm - Inter-electrode Spacing : 2 – 3 mm - Number of selected dipoles : 5	Supports the Biosense Webster NAVISTAR® family of catheters with built-in magnetic sensor for real-time navigation, including the LASSO® NAV Catheter (K093376) with location sensors and the ability to display the catheter's circular loop based on the position of magnetic single axial sensors (SAS) and provide selective pacing through the loop electrodes. Supports the CARTO SOUNDSTAR 3D ultrasound catheter; a location sensing Intracardiac Echo (ICE) catheter with an acoustic array embedded in the catheter tip that allows the acquisition of real time ultrasound images. The location sensor enables the accurate location of the U/S-observed intracardiac anatomies in the CARTO XP EP Navigation System spatial coordinates.	The CARTO proprietary and non-proprietary catheters perform identical electromagnetic sensing functions to the catheters that are compatible for use with VX1. Other systems' catheters may be used to provide real time navigation and/or catheter loop display, selective pacing through the loop electrodes, or ultrasound integration. The difference in specific catheters does not affect the device performance or raise different questions of safety or effectiveness.
Hardware Design and Materials	Off-the-shelf analog / digital converter, computer and monitor, connection cable, acquisition system, proprietary software algorithm.	Off-the-shelf information technology (IT) hardware: computer and monitor, proprietary catheters, patient interface unit and accessories.	Equivalent, but with certain compatible vs. proprietary equipment (e.g., catheters).

Performance Data – Nonclinical Tests:

The Volta Medical VX1 was subjected to extensive non-clinical testing including rigorous verification and validation testing. The Company additionally conducted the following studies:

(1) A Reader Study to evaluate the level of inter-operator agreement after unlimited-time physician visual intra-cardiac atrial DE annotation and determine whether algorithm-enabled classification acceptably correlates with physician annotation. A dataset of 14,370 electrograms were adjudicated by three independent experts and VX1 for the presence or absence of dispersed intra-cardiac atrial electrograms. The study demonstrated that the expert readers both strongly agreed with one another as to the presence or absence of dispersed intra-cardiac atrial electrograms in the evaluated electrogram recordings and that they, similarly, independently agreed with the VX1 adjudication of the presence or absence of intra-cardiac atrial DEs.

(2) A period estimation algorithm testing to assess the performance of the VX1 software against two alternative period estimation approaches: a sophisticated auto-correlation (AC) algorithm and a Fast Fourier Transform (FFT) with Blackman window processing across a dataset of 2,550 electrograms. Overall, the VX1 period estimation algorithm outperformed both the FFT-based and the AC-based algorithms for evaluating noisy and non-periodic electrograms and for estimating the period on the period estimation dataset.

(3) A k-fold cross-validation of VX1 algorithm was performed on the training database of 275,020 1.5 second annotated electrograms. 5-fold cross validation was performed on the model with a resulting accuracy of over 89%.

(4) Limited time annotation testing in which 1,020 electrograms were classified by two annotating experts who were allowed unlimited time to make a classification determination and reach a consensus as to the presence or absence of intra-cardiac atrial dispersion. VX1 performance was compared to the performance of 28 cardiac electrophysiologists who underwent a full-day seminar on spatiotemporal dispersion. The cardiac electrophysiologists each classified 1,020 electrograms as either dispersed or non-dispersed with 17 seconds allotted for each classification. The VX1 algorithm demonstrated superior performance (agreement to the annotating experts) to the cardiac electrophysiologists in identifying dispersed and non-dispersed intra-cardiac atrial electrograms.

Performance Data – Clinical Tests:

An OUS clinical study was performed to evaluate the performance of the VX1 in the detection of intra-cardiac atrial electrograms exhibiting spatiotemporal dispersion during a catheter ablation procedure for atrial fibrillation or atrial tachycardia. The study was aimed at evaluating the usability and efficacy of VX1 for detecting DEs and involved 8 centers, 18 operators, and 300 patients. The results indicate that the implementation of VX1 in a cardiac electrophysiology laboratory is not associated with additional risk or procedure time. Also,

the VX1 device demonstrated comparable performance in locating electrical signal transmission pattern disruptions as the predicate's CFAE module.

Conclusions:

The VX1 device and its predicate both work with standard electrophysiology catheters to aid in mapping the human atria. The predicate device contains several functional modules that are not included in the VX1 device; however, these functions can generally be performed by another device that can be used during the same procedure as the VX1 device. Because mapping can be used independently, the provision of a separate functionality in the VX1 versus an integrated functionality in the predicate does not raise new types of questions or otherwise adversely impact performance, as confirmed in the submitted testing.

Specifically, the VX1 device is substantially equivalent to the CARTO[®] XP System with CARTOPRESS[™] Module. In particular, the VX1 performs an equivalent function to the CFAE Module of the predicate device, and works with mapping systems and compatible catheters to form a system which is equivalent to the predicate system. The VX1 and CFAE module have similar technological characteristics and principles of operation. The signals identified by the VX1 device are of the same nature (multipolar electrograms), and have the same input (intra-cardiac atrial signals) and output (associated dispersion / fractionation). The VX1 has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do 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 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 predicate. Thus, the VX1 device is substantially equivalent.