August 4, 2023

Cath Vision ApS
℅ Sharon Bishop
Director of Regulatory Affairs
Graematter, Inc.
1324 Clarkson Clayton Ctr #332
St. Louis, Missouri 63011

Re: K223787
Trade/Device Name: ECGenius™ System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: July 4, 2023
Received: July 6, 2023

Dear Sharon Bishop:

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,
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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)*
K223787

Device Name
ECGenius™ System

Indications for Use *(Describe)*
The ECGenius™ System is an electrophysiology measurement system and analysis tool used to acquire, filter, digitize, amplify, display, record, and analyze data obtained during electrophysiological studies and related procedures. The system is compatible with a 3rd-party stimulator, intended to be used for diagnostic cardiac stimulation during electrophysiological testing of the heart.

The PVI Analyzer™ feature is a secondary measure of pulmonary vein isolation and should not replace traditional methods of confirming isolation.

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
K223787

ECGenius™ System Summary

Submitter's information

CathVision ApS
Titangade 11
2200 Copenhagen N
Denmark

Contact: Sharon Bishop
Graematter, Inc.
1324 Clarkson Clayton Ctr #332
Ballwin, MO 63011
Phone: 919-724-8978
Date: August 4, 2023

Classification

The classification for the new device is listed below.

21 CFR Reference	Product Code	Class	Generic Device Name	Classification Description
§870.1425	DQK	II	Computer, Diagnostic, Programmable	Programmable diagnostic computer

New device

The new device's indications for use are listed in the table below.

Device Name	Indications for Use
ECGenius™ System	The ECGenius™ System is an electrophysiology measurement system and analysis tool used to acquire, filter, digitize, amplify, display, record, and analyze data obtained during electrophysiological studies and related procedures. The system is compatible with a 3rd-party stimulator, intended to be used for diagnostic cardiac stimulation during electrophysiological testing of the heart. The PVI Analyzer™ feature is a secondary measure of pulmonary vein isolation and should not replace traditional methods of confirming isolation.

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Predicate device

The predicate device for the ECGenius™ System is shown in the table below.

K Number	Product Code	Predicate Device Name	Indications for Use
K220306	DQK	ECGenius™ System	The ECGenius™ System is an electrophysiology measurement system used to acquire, filter, digitize, amplify, display, and record clinical data obtained during electrophysiological studies and related procedures. The system is compatible with a 3rd-party stimulator, intended to be used for diagnostic cardiac stimulation during electrophysiological testing of the heart.

Reference devices

The reference devices for the ECGenius™ System are shown in the table below.

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K Number	Product Code	Predicate Device Name	Indications for Use
K180238	DQK	Carto 3	The intended use of the CARTO® 3 System is catheter-based cardiac electrophysiological (EP) procedures. The CARTO 3 System provides information about the electrical activity of the heart and about catheter location during the procedure. The system can be used on patients who are eligible for a conventional electrophysiological procedure. The system has no special contraindications.
K101331	DQK	Bard LabSystem PRO	The Bard LabSystem ER Laboratory is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, pace mapping and storage of cardiac electrophysiologic data. When integrated with the Philips EP navigator system, the BARD® LabSystem™ PRO EP Recording System is designed to acquire, analyze, and display 3D electro- anatomical maps of the human heart. The maps are constructed using intracardiac electrograms with their respective cardiac locations taken from live x-ray overlay on a patient's 3D cardiac anatomy. Maps may be displayed as electrical activation maps, voltage maps, dominant frequency maps and location maps with user defined measurement values.

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Device description

The ECGenius™ System is an electrophysiology (EP) recording system used in EP procedures as part of the diagnosis and treatment of cardiac arrhythmias. ECGenius™ System (with ECGenius™ Software V3.0) is similar to ECGenius™ System (with ECGenius™ Software V2.0) but has two additional software modules.

The Signal Complexity™ software module analyzes various properties of the signals from a connected 10-pole catheter and visualizes them on a colormap. No clinical claims are made for Signal Complexity™.

The PVI Analyzer™ software module aids the user in evaluating the isolation status of a pulmonary vein. The module performs automated real time analysis of electrograms (EGM) from compatible connected 8- or 10-pole circular mapping catheters during a PVI procedure. The result of the analysis (Isolated vs Non-isolated) is presented in a visual plot to the user. The PVI Analyzer™ feature is a secondary measure of pulmonary vein isolation and should not replace traditional methods of confirming isolation.

The ECGenius™ System consists of an electrophysiology amplifier (Cube Amplifier), recording system software (ECGenius™ Software) running on a PC, and additional components including external cable assemblies, PC monitors, and a printer. Electrophysiological signals are filtered, amplified, and digitized in the Cube Amplifier, and sent to the PC and recording system software for further processing, analysis, visualization, and recording. The ECGenius™ System works in an EP laboratory or operating room in hospitals in conjunction with several other devices from other manufacturers.

The ECGenius™ System includes the following items:

- Cube Amplifier
- Two IECG pin box cables for connection of catheters
- Surface ECG trunk cable and ECG leadwires
- Blood pressure cables
- Data cable to host computer
- Stimulator cable
- Analog-out and analog-in cables
- ECGenius™ Software with the PVI Analyzer™ and Signal Complexity™ software modules
- Host computer (PC), monitors and printer
- Isolation transformers

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Characteristics - comparison with predicate device

The table below lists the characteristics for both the new and predicate devices.

ATTRIBUTE	SUBJECT DEVICE ECGenius™ System (with ECGenius™ Software V3.0)	PREDICATE DEVICE ECGenius™ System (with ECGenius™ Software V2.0) K220306	COMPARISON
Indications for use	The ECGenius™ System is an electrophysiology measurement system and analysis tool used to acquire, filter, digitize, amplify, display, record, and analyze data obtained during electrophysiological studies and related procedures. The system is compatible with a 3rd-party stimulator, intended to be used for diagnostic cardiac stimulation during electrophysiological testing of the heart. The PVI Analyzer™ feature is a secondary measure of pulmonary vein isolation and should not replace traditional methods of confirming isolation.	The ECGenius™ System is an electrophysiology measurement system used to acquire, filter, digitize, amplify, display, and record clinical data obtained during electrophysiological studies and related procedures. The system is compatible with 3rd-party stimulator, intended to be used for diagnostic cardiac stimulation during electrophysiological testing of the heart.	Subject device includes additional analysis tools, and the term “analyze” is added to the indications for use. The change does not impact intended use or safety and effectiveness.
FDA Product code	DQK	DQK	Same

ATTRIBUTE	SUBJECT DEVICE ECGenius™ System (with ECGenius™ Software V3.0)	PREDICATE DEVICE ECGenius™ System (with ECGenius™ Software V2.0) K220306	COMPARISON
Classification	Programmable diagnostic computer, 21 CFR §870.1425	Programmable diagnostic computer, 21 CFR §870.1425	Same
Population	Adults PVI Analyzer™ is indicated for adults in sinus rythmn undergoing their first PVI treatment	Adults	Comparable - PVI Analyzer™ (analysis tool) is indicated for adults in sinus rythmn undergoing their first PVI treatment. Does not impact safety and effectiveness.
Recorder Software	ECGenius™ Software V3.0	ECGenius™ Software V2.0	The recorder software in the subject device is an evolution of the recorder software in the predicate device.
CARDIALYTICS™ software plug-ins	Signal Complexity™ PVI Analyzer™	None	The recorder software for the subject device includes two new software modules (analysis tools). Does not impact safety and effectiveness.
Amplifier Dimensions WxDxH (cm)	43x43x31	43x43x31	Same
Temperature Operating	+10°C to +30°C	+10°C to +30°C	Same
Temperature Transport/Storage	-15°C to +50°C	-15°C to +50°C	Same
Humidity Operating	30 - 75 % rH (non-condensing)	30 - 75 % rH (non-condensing)	Same

ATTRIBUTE	SUBJECT DEVICE ECGenius™ System (with ECGenius™ Software V3.0)	PREDICATE DEVICE ECGenius™ System (with ECGenius™ Software V2.0) K220306	COMPARISON
Humidity Transport/Storage	10 - 95 % rH (non-condensing)	10 - 95 % rH (non-condensing)	Same
Power Requirements	100 - 240 V AC, 50 - 60 Hz	100 - 240 V AC, 50 - 60 Hz	Same
Current Draw	0.7A @ 110VAC, 0.35A @ 240VAC	0.7A @ 110VAC, 0.35A @ 240VAC	Same
Sampling Rate	2kHz	2kHz	Same
CMRR	> 120dB	> 120dB	Same
Input Impedance	>2.5MΩ	>2.5MΩ	Same
IECG Inputs	128 channels + 2 references	128 channels + 2 references	Same
IECG Switching	Each channel can be either bipolar or unipolar with manual switching	Each channel can be either bipolar or unipolar with manual switching	Same
IECG High Pass Filter	None 0.01 Hz 0.05 Hz 0.1 Hz 0.5 Hz 1 Hz 10 Hz 30 Hz 100 Hz	None 0.01 Hz 0.05 Hz 0.1 Hz 0.5 Hz 1 Hz 10 Hz 30 Hz 100 Hz	Same
IECG Low Pass Filter	50 Hz 100 Hz 250 Hz 500 Hz None	50 Hz 100 Hz 250 Hz 500 Hz None	Same
IECG RF Filtering	All inputs	All inputs	Same

ATTRIBUTE	SUBJECT DEVICE ECGenius™ System (with ECGenius™ Software V3.0)	PREDICATE DEVICE ECGenius™ System (with ECGenius™ Software V2.0) K220306	COMPARISON
IECG Scale	Between 1.25 and 5120 mm/mV – discrete intervals	Between 1.125 and 5120 mm/mV – discrete intervals	Same
IECG Saturation Recovery	< 1 s (auto reset)	< 1 s (auto reset)	Same
IECG Power-line Filter	Notch 50/60Hz Adaptive Notch None	Notch 50/60Hz None	Similar. Subject device has in additional a (software based) Adaptive Notch filter. Does not impact safety and effectiveness.
IECG Dynamic Range	±100 mV	±100 mV	Same
IECG Baseline Correction	±1000 mV	±1000 mV	Same
ECG Inputs	10 ECG inputs (= 12 leads)	10 ECG inputs (= 12 leads)	Same
ECG High Pass Filter	None 0.01 Hz 0.05 Hz 0.1 Hz 0.5 Hz 1 Hz 10 Hz	None 0.01 Hz 0.05 Hz 0.1 Hz 0.5 Hz 1 Hz 10 Hz	Same
ECG Low Pass Filter	100 Hz 150 Hz 250 Hz 500 Hz None	100 Hz 150 Hz 250 Hz 500 Hz None	Same
ECG RF Filtering	All inputs	All inputs	Same

ATTRIBUTE	SUBJECT DEVICE ECGenius™ System (with ECGenius™ Software V3.0)	PREDICATE DEVICE ECGenius™ System (with ECGenius™ Software V2.0) K220306	COMPARISON
ECG Scale	Between 1.25 and 5120 mm/mV – discrete intervals	Between 1.25 and 5120 mm/mV – discrete intervals	Same
ECG Saturation Recovery	< 1 s (auto reset)	< 1 s (auto reset)	Same
ECG Power-line Filter	Notch 50/60Hz None	Notch 50/60Hz None	Same
ECG Dynamic Range	±10mV	±10mV	Same
Baseline Correction	±300mV	±300mV	Same
Auxiliary Inputs Channels	4 pressure 2 auxiliary (analog in)	4 pressure 2 auxiliary (analog in)	Same
Output channels	12 lead ECG produced	12 lead ECG produced	Same
Isolated Stimulus Channels, Stimulator	2 (external stimulator)	2 (external stimulator)	Same
Backup	Connect catheters to stimulator bypass connections	Connect catheters to stimulator bypass connections	Same
Display Ablation Parameters	Connection to RF ablation generator(s)	Connection to RF ablation generator(s)	Same

ATTRIBUTE	SUBJECT DEVICE ECGenius™ System (with ECGenius™ Software V3.0)	PREDICATE DEVICE ECGenius™ System (with ECGenius™ Software V2.0) K220306	COMPARISON
Standards	IEC 60601-1: 2005+A2:2020 (*) IEC 60601-1-2: 2014+ A1:2020 (*) IEC 60601-1-6:2010+A1:2014 IEC 60601-2-27: 2014 IEC 60601-2-34: 2014 IEC 62366-1: 2015 IEC 62304: 2006+ A1:2015	IEC 60601-1: 2005+A1:2012 IEC 60601-1-2: 2014 IEC 60601-1-6:2010+A1:2014 IEC 60601-2-27: 2014 IEC 60601-2-34: 2014 IEC 62366-1: 2015 IEC 62304: 2006+ A1:2015	Same. However, subject device complies with newer versions (*)
Leakage Current Patient	< 10 µA	< 10 µA	Same
Leakage Current Patient (single fault conditions)	< 50 µA	< 50 µA	Same
Leakage Current Touch current	< 100 µA	< 100 µA	Same

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PVI Analyzer comparison with reference device

The table below lists the characteristics for the PVI Analyzer module and reference device.

Reference Devices	PVI Analyzer	Reference Description	Comparison
K180238 Carto 3	PVI Analyzer™ analyses the signals from intracardiac mapping catheter to produce a value that is related through a decision threshold to a binary classification of the Isolation Status. The PVI Analyzer™ feature is a secondary measure of pulmonary vein isolation and should not replace traditional methods of confirming isolation.	Carto VISITAG Module calculates a tag index value using electrophysiological parameters to indicate when high and low index thresholds are met during RF application.	Both devices use as input measurements from intracardiac catheters, combining those measurements in a single value/index and applies a threshold to output a classification of the measurements to the user. The user uses the value/index and the classification as supplementary information/secondary measure to support an ablation strategy during a pulmonary vein isolation procedure.

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Signal Complexity comparison with reference devices

The table below lists the characteristics for the Signal Complexity module and reference devices.

Reference Devices	Signal Complexity	Reference Description	Comparison
K180238 Carto 3	The Signal Complexity™ module generates a fractionation index.	The Carto CFAE module generates color-coded maps displaying areas of CFAEs according to the degree of signal fractionation.	Both devices are creating a measurement of fractionation.
K101331 Bard LabSystem PRO	Signal Complexity™ module - analyses electrical activations and dominant frequency from an intracardiac catheter and displays them in a colormap.	Acquires, analyzes, and displays electrical activation maps, voltage maps, dominant frequency maps, and location maps with user defined measurement values.	Both devices make measurements of electrical activations and dominant frequency and displays them in a colormap. The Signal Complexity™ module further calculates a dominant frequency gradient measurement whereas the reference device displays measurements of dominant frequencies of different locations in a map.
	The Signal Complexity™ module calculates cycle length.	Cycle length information associated with each location.	Both devices measure and display cycle length.

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Performance testing

The following performance testing was conducted to demonstrate substantial equivalence to the predicate device:

- Software verification and validation
- Cybersecurity testing
- Operating environment verification
- Biocompatibility
- Packaging
- Cleaning
- Human factors/usability
- Shelf life

Guidance documents referenced for testing

The following guidance documents were referenced for testing:

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- Content of Premarket Submissions for Management of Cybersecurity in Medical Device (2014 and 2018)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices
- Off-The-Shelf Software Use in Medical Devices
- Applying Human Factors and Usability Engineering to Medical Devices
- Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”

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Consensus standards used for testing

The following consensus standards were referenced for testing.

- IEC 60601-1:2005+A2:2020 Edition 3.2
- IEC 60601-1-2:2014+A1:2020 Edition 4.1
- IEC 60601-2-27 Edition 3.0 2011-03 (see note)
- IEC 60601-2-34 Edition 3.0 2011-05 (see note)
- IEC 62366 Edition 1.0 2015-02
- IEC 62304 Edition 1.1 2015-06
- ISO 10993-1 5th edition 2018-8

Note: As the ECGenius™ System is not intended as a patient monitor system, clauses relating to alarm systems do not apply.

Conclusion

A comparison has been conducted of the intended use/indications for use, technological characteristics (including fundamental operating principle, functional characteristics, design features and performance characteristics) and labelling for the ECGenius™ System with ECGenius™ Software V3.0 and the ECGenius™ System with ECGenius™ Software V2.0. The technological differences between the subject and predicate devices are the PVI Analyzer™ and Signal Complexity™ modules. These modules do not present different questions of safety or effectiveness because they are only intended to provide the physician with additional information that supplements common clinical practice and do not alter the Intended Use.

Thus, the ECGenius™ System with ECGenius™ Software V3.0 is substantially equivalent to the ECGenius™ System with ECGenius™ Software V2.0 predicate device (K220306).