May 3, 2022

CathVision ApS
℅ Sharon Bishop
Director of Regulatory Affairs
Graematter, Inc.
1324 Clarkson Clayton Ctr #332
Ballwin, Missouri 63011

Re: K220306
Trade/Device Name: ECGenius™ System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: January 31, 2022
Received: February 2, 2022

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 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)*
K220306

Device Name
ECGenius™ System

Indications for Use *(Describe)*
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.

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

ECGenius™ Summary

Submitter's information

CathVision ApS
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2200 Copenhagen N
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Contact: Sharon Bishop
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Ballwin, MO 63011
Phone: 919-724-8978
Date: 31 January 2022

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 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.

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
K183266	DQK	Schwarzer CardioTek EP-TRACER	The EP-TRACER System is an electrophysiology measurement system used to acquire, filter, digitize, amplify, display, and record signals obtained during electrophysiological studies and related procedures. The system allows the user to monitor, display and record the signals. The system incorporates a stimulator intended to be used for diagnostic cardiac stimulation during electrophysiological testing of the heart

Device description

The ECGenius™ System consists of an electrophysiology amplifier (commercial name "Cube Amplifier" in the technical documentation also called "EP Amplifier" or "EPAMP"), recording system software (commercial name "ECGenius™ Software" in technical documentation also called "Recorder Software" or "Recorder SW" or abbreviated as "RecSW") running on a PC, and additional components including external cable assemblies, PC monitors, and a printer. Electrophysiological signals are filtered, amplified, digitized in the Cube Amplifier, and sent to the PC and recording system software for further processing, 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 is an electrophysiology (EP) recording system used in EP procedures as part of the diagnosis and treatment of cardiac arrhythmias. 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
- Host computer (PC), monitors and printer

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

ATTRIBUTE	SUBJECT DEVICE ECGenius™ System K220306	PREDICATE DEVICE Schwarzer CardioTek GmbH EP-TRACER K183266	COMPARISON
Indications for use	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.	The EP-TRACER System is an electrophysiology measurement system used to acquire, filter, digitize, amplify, display, and record signals obtained during electrophysiological studies and related procedures. The system allows the user to monitor, display and record the signals. The system incorporates a stimulator intended to be used for diagnostic cardiac stimulation during electrophysiological testing of the heart.	Similar except that the ECGenius™ System does not incorporate a stimulator
FDA Product code	DQK	DQK	Same
Classification	Programmable diagnostic computer, 21 CFR §870.1425	Programmable diagnostic computer, 21 CFR §870.1425	Same
Amplifier Dimensions WxDxH (cm)	43x43x31	28x27x12	Different but both can be installed and used in an EP lab
Temperature Operating	+10°C to +30°C	+10°C to +30°C	Same
Temperature Transport/Storage	-15°C to +50°C	-29°C to +66°C	As both systems are intended for use in air-conditioned hospital EP labs and operating

ATTRIBUTE	SUBJECT DEVICE ECGenius™ System K220306	PREDICATE DEVICE Schwarzer CardioTek GmbH EP-TRACER K183266	COMPARISON
Humidity Operating	30 - 75 % rH (non-condensing)	20 - 80 % rH (non-condensing)	rooms, the minor difference in environmental humidity is insignificant. Similarly, both systems are able to withstand the expected temperature and humidity variations to be experienced during transport/storage.
Humidity Transport/Storage	10 - 95 % rH (non-condensing)	< 95 % rH (non-condensing)	
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	15A @ 115V, 7A @ 230V	ECGenius™ System consumes less power
Sampling Rate	2kHz	1 kHz	The ECGenius™ System is capable of acquiring data at 2kHz, with a common mode rejection ratio (CMRR) of >120dB, where the EP-TRACER CMRR is >100dB. The EP-TRACER claims that typical input impedance is 20MΩ. CathVision has tested the ECGenius™ System to verify that the input impedance is >2.5MΩ, in accordance with IEC 60601-2-27 §201.12.1.101.3. Typical values have not been established.
CMRR	> 120dB	> 100 dB	
Input Impedance	>2.5MΩ	Typical 20 MΩ	
IECG Inputs	128 channels + 2 references	84 channels	The two systems are able to acquire multiple intracardiac ECG signals, and all specifications for the ECGenius™ System are at least as good as for the EP-TRACER. Specifically, the ECGenius™ System has a greater range of high-pass and low-pass filter choice, a larger input range and offset, plus a greater maximum gain.
IECG Switching	Each channel can be either bipolar or unipolar with manual switching	Each channel can be either bipolar or unipolar with manual switching	
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	0.05 Hz 0.2 Hz 40 Hz 80 Hz	
IECG Low Pass Filter	50 Hz	350 Hz	

ATTRIBUTE	SUBJECT DEVICE ECGenius™ System K220306	PREDICATE DEVICE Schwarzer CardioTek GmbH EP-TRACER K183266	COMPARISON
	100 Hz 250 Hz 500 Hz None		
IECG RF Filtering	All inputs	All inputs	
IECG Gain	Between 0.01 and 5120 mm/mV – discrete intervals	Between 0 and 255 mm/mV – continuous	
IECG Saturation Recovery	< 1 s (auto reset)	< 1 s (manual reset)	
IECG Notch Filter	50/60Hz None	50/60 Hz None	
IECG Dynamic Range	±100 mV	±5 mV	
IECG Baseline Correction	±1000 mV	±300 mV	
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	0.05 Hz 0.2 Hz	The two systems are able to acquire multiple surface ECG signals, and all specifications for the ECGenius™ System are at least as good as for the EP- TRACER. Specifically, the ECGenius™ System has a greater range of high-pass and low-pass filter choice, a larger input range and offset, plus a greater maximum gain. Note: the EP-TRACER claims to support 12 ECG ‘channels’, but the number corresponds to the
ECG Low Pass Filter	100 Hz 150 Hz 250 Hz 500 Hz None	150 Hz	
ECG RF Filtering	All inputs	All inputs	
ECG Gain	Between 0.01 and 5120 mm/mV – discrete intervals	Between 0 and 255 mm/mV - continuous	

ATTRIBUTE	SUBJECT DEVICE ECGenius™ System K220306	PREDICATE DEVICE Schwarzer CardioTek GmbH EP-TRACER K183266	COMPARISON
ECG Saturation Recovery	< 1 s (auto reset)	< 1 sec (manual reset)	ECG leads (derived from the standard 10 electrodes).
ECG Notch Filter	50/60Hz None	50/60 Hz None	
ECG Dynamic Range	±10mV	±5 mV	
Baseline Correction	±300mV	±300 mV	
Auxiliary Inputs Channels	4 pressure 2 auxiliary (analog in)	6 auxiliary (pressure)	Both systems offer 6 input channels. In the case of the EP-TRACER, these are all pressure inputs. For the ECGenius™ System, 4 channels are dedicated to pressure signals, but the remaining two can be utilized for any type of analog signal.
Output channels	12 lead ECG produced	12 lead ECG produced	The EP-TRACER provides the user with analog output signals representing the 12 ECG leads. In comparison, the ECGenius™ System allows the user to output 12 ECG signals and 1 bipolar intracardiac ECG signal. The ECGenius™ System also has a single channel analog output dedicated to the ECG lead II. Although the systems differ in the signals made available, this feature is not part of the core functionality of an EP recording system and the differences are not significant.
Isolated Stimulus Channels, Stimulator	2 (external stimulator)	2	The EP-TRACER contains an internal cardiac stimulator, with 2 independent channels, each of which can be assigned, under software control, to any of the intracardiac channels. ECGenius™ System is compatible with an

ATTRIBUTE	SUBJECT DEVICE ECGenius™ System K220306	PREDICATE DEVICE Schwarzer CardioTek GmbH EP-TRACER K183266	COMPARISON
			external 2-channel stimulator, whereby each stimulator signal can be independently routed, under software control, to any of the intracardiac channels.
Backup	Connect catheters to stimulator bypass connections	Use external backup stimulator	For the EP-TRACER, the user is expected to use an external backup stimulator in the event of the system failing. For the ECGenius™ System, a system failure could result in the user not being able to select the correct routing for the stimulation signal. In this case, the user is expected to connect the appropriate electrodes to the ECGenius™ System's dedicated stimulator bypass connections (which are hardwired to the external stimulator).
Display Ablation Parameters	Connection to RF ablation generator(s)	Connection to RF ablation generator(s)	Same
Standards	IEC 60601-1: 2005+A1:2012 IEC 60601-1-2: 2014 IEC 60601-1-6: 2010+A1:2013 IEC 60601-2-27: 2011 IEC 60601-2-34: 2011 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+A1:2013 IEC 60601-2-27: 2011 IEC 60601-2-34: 2011 IEC 62366: 2007+A1:2014 IEC 62304: 2006	The same standards are used; however, some have been updated for the ECGenius™ System
Leakage Current Patient	< 10 µA	< 10 µA	Same

ATTRIBUTE	SUBJECT DEVICE ECGenius™ System K220306	PREDICATE DEVICE Schwarzer CardioTek GmbH EP-TRACER K183266	COMPARISON
Leakage Current Patient (single fault conditions)	< 50 µA	< 50 µA	Same
Leakage Current Touch current	< 100 µA	< 100 µA	Same

Performance testing	The following performance testing was conducted to demonstrate substantial equivalence to the predicate device: • Software verification and validation • Operating environment verification • Biocompatibility • Packaging • Cleaning • Human factors/usability • Shelf life
Guidance documents referenced for testing	The following guidance documents were referenced for testing: • Content of Premarket Submissions for Management of Cybersecurity in Medical Device – Draft Guidance for Industry and FDA staff • Content of Premarket Submissions for Management of Cybersecurity in Medical Device • 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
Consensus standards used for testing	The following consensus standards were referenced for testing. All except IEC 60601-1:2005+A1:2012 are FDA-recognized consensus standards. • IEC 60601-1:2005+A1:2012 (not FDA-recognized but similar to FDA-recognized ANSI AAMI ES60601-1) • IEC 60601-1-2:2014 4th Edition • 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.

Summary and conclusion

Performance testing for this submission has been limited to bench testing. There are no animal or clinical studies.

In summary:

- Verification and validation of the design of the ECGenius™ System has been conducted in accordance with ISO 13485:2016 and the Quality System Regulations (21CFR820) section 820.30.
- The ECGenius™ System has been tested against and complies with the multiple international standards listed herein.

The EP-TRACER and the ECGenius™ System share the same intended use as a cardiology electrophysiology recording system. The most important characteristics for fulfilling this use are those related to the acquisition of intracardiac and surface ECG signals. The ECGenius™ System exhibits performance characteristics that are substantially equivalent to the EP-TRACER.

For the majority of other characteristics, the ECGenius™ System is the same or similar in specification to the EP-TRACER as documented in its 510(k) summary. The ECGenius™ System, like the EP-TRACER, is compliant with all applicable standards.

Based on the above, it is considered that the ECGenius™ System is substantially equivalent to the EP-TRACER System from Schwarzer Cardiotek (K183266).