DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 5, 2016

CardioTek, B.V.
% Melissa Walker
President & CTO
Graematter, Inc.
1324 Clarkson Clayton Center #332
St Louis, Missouri 63011

Re: K161245
Trade/Device Name: EP-Tracer System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: June 13, 2016
Received: June 22, 2016

Dear Melissa Walker:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161245

Device Name
EP TRACER System

Indications for Use *(Describe)*

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

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.

Section 5: 510(k) Summary per 21CFR §807.92

EP TRACER System Summary

Submitter's information

Contact: Oliver Roth
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74076 Heilbronn / Germany

Contact: Melissa Walker
Graematter, Inc.
1324 Clarkson Clayton Ctr #332
Ballwin, MO 63011
Phone: 636-405-7498
Date: 02/14/2016

Device/ classification name

Device Name:
The EP-TRACER System is a Class 2 device (product code DQK).

Classification/Common name:
- Programmable diagnostic computer, 21 CFR §870.1425,

The marketed device(s) to which substantial equivalence is claimed:
- EP-TRACER System, K134044

Device description

The EP-TRACER System is a computerized electrophysiology measurement system designed for both regular and experimental EP studies.

The EP-TRACER System is comprised of these major components,

1. EP-TRACER hardware – Amplifier/stimulator
2. EP-TRACER Software – Software pre-installed

Indications for use

"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".

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EP TRACER System Summary, Continued

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

Device Characteristic	Predicate Device EP-TRACER V1.05 K134044	New Device EP-TRACER V2 K161245
Amplifier Dimensions (with integrated stimulator) WxDxH	38 channels: 28x27x7 in cm 70/102 channels: 28x27x12 in cm	Same
Environmental Specifications		
Temperature Operating	+10°C to +30°C	Same
Temperature Transport/Storage	-29°C to +66°C	Same
Humidity Operating	20 - 80 % rH (non-condensing)	Same
Humidity Transport/Storage	< 95 % rH (non-condensing)	Same
Power Specifications		
Power Requirements	100 - 240 V AC, 50 - 60 Hz	Same
Power Input	38 channels: +5 V, 0.3 A & +12 V, 0.9 A 70 channels: +5 V, 0.3 A & +12 V, 1.5 A 102 channels: +5 V, 0.3 A & +12 V, 2 A	Same
Design		
Sampling and Hold	Each channel sampled prior the acquisition	Same
Sampling Rate	1 kHz	Same
CMRR	> 100 dB	Same
Input Impedance	Typical 20 MΩ	Same
Leakage Current		
Patient Source	< 10 µA	Same
Patient Sink	< 10 µA	Same
Patient Sink (measured at patient leads under single fault conditions)	< 50 µA	Same
Chassis Leakage	< 100 µA	Same
ECG Input		
Outputs	12 lead ECG produced	Same
High Pass Filter	0.05 Hz, 0.2 Hz	Same
Low Pass Filter	150 Hz	Same
RF Filtering	All inputs	Same
Gain	Between 0 and 255 mm/mV - continuous	Same
Saturation Recovery	< 1 sec (manual reset)	Same
Notch Filter	Power line (50/60 Hz)	Same
Dynamic Range	±5 mV	Same
Baseline Correction	±300 mV	Same

Device Characteristic	Predicate Device EP-TRACER V1.05 K134044	New Device EP-TRACER V2 K161245
Input/ Output		
Inputs 32/38 channels	20 intracardiac channels, 6 auxiliary channels, 12 ECG channels	Same
Inputs 64/70 channels	52 intracardiac channels, 6 auxiliary channels, 12 ECG channels	Same
Inputs 102 channels	84 intracardiac channels, 6 auxiliary (pressure) channels, 12 ECG channels	Same
Outputs	No outputs	Same
Switching	Each channel can be either bipolar or unipolar with manual switching	Same
High Pass Filter	0.05 Hz, 0.2 Hz, 40 Hz, 80 Hz	Same
Low Pass Filter	350 Hz	Same
RF Filtering	All inputs	Same
Gain	Between 0 and 255 mm/mV – continuous	Same
Saturation Recovery	< 1 s (manual reset)	Same
Notch Filter	Power line (50/60 Hz)	Same
Dynamic Range	±5 mV	Same
Baseline Correction	±300 mV	Same
Stimulator (integrated into device)		
Isolated Stimulus Channels	2	Same
Pulse Amplitude		
Range	0 - 25.5 mA into 1000 Ω load	Same
Increment	0.1 ms	Same
Accuracy	±0.15 ms	Same
Pulse Duration		
Range	0.1 - 9.9 ms	Same
Increment	0.1 ms	Same
Accuracy	±0.15 ms	Same
Inter-Stimulus Interval (ISI)		
Range	10 - 9999 ms	Same
Range (Burst)	10 - 9999 ms	Same
Increment	10 ms	Same
Sequential Delay (AV)		
Range	11 - 250 ms	Same
Increment	1 ms	Same
Programmed Protocols	Preprogrammed protocols: BASIC 1 (induction) BASIC 2 (termination) BASIC 3 (backup) ACUTE Multi-Sx	Same
Programmed Protocols	Pace Automatic mode Wenkebach mode User defined protocols	Same

Device Characteristic	Predicate Device EP-TRACER V1.05 K134044	New Device EP-TRACER V2 K161245
Programmable Protocol Key	10	Same
Number of Extra-Stimuli	5 (S2 - S6)	Same
Sensing (ECG Synchronization)		
Automatic or Manual Trigger Setting – Sensitivity	Internal from any surface or intra-cardiac channel	Same
Automatic or Manual Trigger Setting – Trigger lockup (refractory time)	5 - 5000 ms	Same
Automatic or Manual Trigger Setting – ECG Delay	5 - 5000 ms	Same
Additional Outputs	No	Same
Power Source	Integrated with amplifier 38 channels: +5 V, 0.3 A & +12 V, 0.9 A 70 channels: +5 V, 0.3 A & +12 V, 1.5 A 102 channels: +5 V, 0.3 A & +12 V, 2 A	Same
Pacing Channels		
Isolated Channels	(i) atrial and (ii) ventricular and (iii) emergency fixed pace output to atrium and ventricle	Same
Circuit Isolation	Compliant with IEC 60601-1, Class CF, 5 kV, common & differential mode	Same
Computer Controlled Stimulus Pulses		
Current	0 - 25.5 mA into 1000 Ω load	Same
Current Steps	0.1 mA	Same
Accuracy	±0.1 mA	Same
Pulse duration	Pulse width 0.1 - 9.9 ms, steps of 0.1 ms	Same
Accuracy	±0.1 mA	Same
Load Impedance	1000 Ω	Same
Max. Output Voltage	25 V	Same
Inter-Stimulus Intervals		
S1 Range	10 - 9999 ms	Same
Stability	Quartz computer clock, ±30 parts per million at +25°C	Same
Extra-Stimuli	5 (S2 - S6)	Same
Coupling Interval	30 - 9990 ms	Same
Accuracy	±10 ms	Same
Protocol Automation		
Auto decrement/ increment	Yes	Same
Backup Manually Controlled Stimulation	Use external backup stimulator	Same
Emergency Backup Pacing	Use external backup stimulator	Same

Device Characteristic	Predicate Device EP-TRACER V1.05 K134044	New Device EP-TRACER V2 K161245
Compliance with Standards		
Standards	EN 60601-1 EN 60601-1-2	Same
Device Directive	European Union Medical Device Directive (CE Marked)	Same
Environmental/ Electrical Specifications		
Operating Temperature	+10°C to +30°C	Same
Storage Temperature	-29°C to +66°C	Same
Operating Humidity	20 - 80 % rH (non-condensing)	Same
Storage Humidity	< 95 % rH (non-condensing)	Same
Max. Current Draw	15 A/115 V, 7 A/230 V	Same
Chassis Leakage Current	< 100 µA	Same
Advanced Features		
Display Ablation Parameters	Connection to RF ablation generator(s)	Same
Certification		
MDD Device Class	Class IIb	Same
IEC 60601-1	Certified	Same
EMC Compliance	Certified	Same
CE Marking	Certified CE 0197	Same
US Regulations	K134044	Current submission
System Dimensions		
W x D x H	Customer Option Mobile Cart: 100x80x170 cm Mobile Desk: 125x80x150 cm Control Desk: customer defined Laptop: customer defined	Same
Software		
Programming language	Borland Delphi 5	Visual C#
Component library	VCL Framework (Visual Component Library)	.NET
Software architecture	Single Threaded	Multi Threaded
Drawing method	2D	3D
License concept	Text file	Dongle
Context sensitive help texts	No	Mouse over context help
Operating concept	Menus and short-cuts	Menus, short-cuts and display elements (i.e. buttons)
Language support	English (full), partial support for other languages	Full multi language support

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EP TRACER System Summary, Continued

Performance testing

The updated version of the EP-TRACER system and software (V2.0) maintains the capabilities in the previous version, adding user interface enhancements.

Testing has been conducted through software and/or user verification/validation protocols to ensure the EP TRACER System meets its intended use and user needs.

Electrical safety and electromagnetic compatibility testing shown in the table below was performed. All tests passed.

Test	Results
Radiated emission; Conducted emission; Radiated immunity; Conducted immunity	Pass
Conducted emission (harmonics); Radiated immunity (PMF); Conducted immunity	Pass
IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012	Pass
Amendment - IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012	Pass
IEC 60601-1-6:2010 (Third Edition) + A1:2013	Pass
IEC 62366:2007 (First Edition) + A1: 2014 for use in conjunction with IEC 60601-1-6: 2010	Pass
IEC 60601-1-27:2011 (Third Edition) for use in conjunction with IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007)	Pass
IEC 60601-2-34 (Third Edition): 2011	Pass

Conclusion

Based on the technical characteristics and the results of the performance testing, the EP TRACER V2.0 is substantially equivalent to V1.05.