August 8, 2018

BioSig Technologies
Tiffini Wittwer
Regulatory
12424 Wilshire Blvd, Suite 745
Los Angeles, California 90025

Re: K180805
Trade/Device Name: Pure EP
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: June 13, 2018
Received: June 21, 2018

Dear Tiffini Wittwer:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180805

Device Name
PURE EP™

Indications for Use *(Describe)*
PURE EP™ is a computerized system intended for acquiring, digitizing, amplifying, filtering, measuring and calculating, displaying, recording and storing of electrocardiographic and intracardiac signals for patients undergoing electrophysiology (EP) procedures in an EP laboratory under the supervision of licensed healthcare practitioners who are responsible for interpreting the data.

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.

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 K180805

Table 1: 510(k) Summary

Submitter:	Biosig Technologies, Inc. 12424 Wilshire Blvd, Suite 745 Los Angeles, CA 90025
Contact Person:	Tiffini Diage Regulatory Affairs Consultant Phone: 707.799.6732 E-mail: tdiage@raechelon.com
Date Of Submission:	March 26, 2018
Trade Name:	PURE EP™
Common Name:	Programmable diagnostic computer / electrophysiology system
Classification:	Class II, per 21 CFR 870.1425
Product Code:	DQK
Predicate Device(s):	The subject device is equivalent to the following devices: • K130626 GE Healthcare; CardioLab (other systems included in cleared 510(k) application)
Device Description:	PURE EP™ is a system consists of two main parts: the amplifier, and the personal computer (PC), which are connected over a high-speed fiber optic cable. The patient is connected to the amplifier via a set of supplied ECG cables and commercially available intracardiac (IC) catheters. The amplifier includes hardware and embedded software necessary for acquiring ECG and IC signals from patients. The device is not intended for active patient monitoring. It consists of one ECG and seven IC modules designed to acquire 12-lead ECG and 56 IC signals and send the digitized data to the PC. The PC has preinstalled PURE-EP software and is connected to display monitors. The pre-installed software provides visualization of received data from the amplifier on real-time and review screens. It also includes a signal processing module that provides various filter options for real-time and review screens.
Indication for Use:	PURE EP™ is a computerized system intended for acquiring, digitizing, amplifying, filtering, measuring and calculating, displaying, recording and storing of electrocardiographic and intracardiac signals for patients undergoing electrophysiology (EP) procedures in an EP laboratory under the supervision of licensed healthcare practitioners who are responsible for interpreting the data.

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Substantial Equivalence Comparison

Item	Predicate Device GE CardioLab	Subject Device PURE EP™
510(k)	K130626	K180805
Class	II	II
Product Code	DQK	DQK
Intended Use and Indications for Use (IFU)	CardioLab System is intended for the acquiring, filtering, digitizing, simplifying, measuring and calculating, displaying, recording and monitoring of clinical data from adult and pediatric patients. CardioLab System is configurable. Clinical data includes: ECG waveforms, intracardiac signals, stimulus data, ablation data, pulse oximetry (SpO2), respiration rate, CO2 (EtCO2), temperature, and invasive and noninvasive blood pressure. Physiological parameters such as diastolic, systolic, mean pressure, heart rate, and cycle length are derived form the signal data, displayed, and recorded. The data is entered manually or acquired via interfaced devices and/or information systems and may be used for report generation.	PURE EP is a computerized system intended for acquiring, digitizing, amplifying, filtering, measuring and calculating, displaying, recording and storing of electrocardiographic and intracardiac signals for patients undergoing electrophysiology (EP) procedures in an EP laboratory under the supervision of licensed healthcare practitioners who are responsible for interpreting the data.
Target Population	Clinical data from adult and pediatric patients.	Patients undergoing EP studies in an EP lab.
Anatomical Site	Multiple, including cardiac signals	Cardiac signals
Where used	Multiple hospital and clinical settings including EP labs	EP labs
Energy Used/Delivered	No energy delivered to patient	No energy delivered to patient
Processor/Data Storage	Intel Pentium IV Xeon or greater processor	Intel i7 quad-core CPU
	512 MB of Ram	16 GB of Ram
	2 x 40 GB hard drives	1 TB
	OS: Windows XP Professional	OS: Windows 7

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Item	Predicate Device GE CardioLab	Subject Device PURE EP™
Number of Channels	32/64 96/128	Up to 64
Sampling Rate	2000 samples per second	2000 samples per second
Analog to Digital Converter	12 bit	24 bit
Outputs	12 lead ECG	Same
RF Filtering	All inputs	Same
Bandwidth	0.05-1000 Hz	Same
ECG high pass filter	0.05 Hz, 0.5 Hz, 5.0 Hz	Software programmable at: 0.05 Hz, 0.5 Hz, 1.0 Hz, 5.0 Hz, 20 Hz, 30 Hz, 50 Hz, 200 Hz
ECG low pass filter	100 Hz	Software programmable at: 30 Hz, 40 Hz, 50 Hz, 100 Hz, 150 Hz, 300 Hz, 500 Hz;
IC high pass filter	0.05 Hz, 0.5 Hz, 5.0 Hz, 30 Hz, 100 Hz	Software programmable 0.05 Hz, 0.5 Hz, 1.0 Hz, 5.0 Hz, 20 Hz, 30 Hz, 50 Hz, 200 Hz
IC low pass filter	150 Hz, 500 Hz, 1000 Hz;	Software programmable at: 30 Hz, 40 Hz, 50 Hz, 100 Hz, 150 Hz, 300 Hz, 500 Hz;
Notch Filter	50/60 Hz	60 Hz
Band Pass Filter	Not available	User selected combination of High Pass, Low Pass and Notch Filter
Type CF	0 -.5 Amps Class I	0 -.8 Amps Class I
Operating Temp range	0 to 35° C (32/64 channel;)	10-40° C
Temp storage/transport	-15 to 50 C non- condensing	20-65° C per ISTA 2A 2008
Humidity Operating	95% at 35 C non- condensing	30-75% non-condensing
Humidity Transport/Storage	95% at 35 C non- condensing	20-85% per ISTA 2A 2008
Patient Source	<10 uA	<10 uA

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Item	Predicate Device GE CardioLab	Subject Device PURE EP™
Patient Sink	<10 uA	<10 uA
Patient Sink (measured at patient leads under single fault condition)	<50 uA	<50 uA
Chassis Leakage	<100uA	<100uA
Size	Height = 9.5 inches Depth = 13 inches Width = 13 inches (32/64 channel version)	Height = 16 inches Depth = 14.7 inches Width = 13 inches
Weight	25 lbs (32/64 channel version)	38 lbs

Performance Testing / Safety and Effectiveness:

To verify that device design meets its functional and performance requirements, representative samples of the device underwent software, electrical, and mechanical testing in accordance with the following industry standards.

- ANSI/AAMI/IEC 62366-1:2015; Medical Devices – Part 1: Application of Usability Engineering to Medical Devices.
- AAMI/ANSI/ISO 14971:2007/(R)2010 Medical devices -- Application of risk management to medical devices.
- IEC 60601-1-6: 2013, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
- AAMI/ANSI HE75: 2013, Human Factors Engineering - Design of Medical Devices..
- IEC 62304: 2015, Medical Device Software - Software Life Cycle Processes
- AAMI/ANSI ES60601-1: 2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- AAMI/ANSI IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests.
- Guidance for Industry and FDA Staff:
    - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Issued 5/11/2005)
    - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (Issued 10/2/2014)

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Summary of Clinical Tests:
Similar to the predicate, the subject of this premarket submission, PURE EP™, did not require clinical studies to support substantial equivalence.

Conclusion:
PURE EP™ intended use, indication for use, anatomical sites, and fundamental technology is equivalent to those of the predicate device. Both devices acquire ECG and IC signals via instrument amplification. Both devices use A/D converters and send data to a host PC. Software, electrical safety, system performance testing and user validation demonstrates that the differences between the subject device and the predicate do not introduce any new questions of safety and effectiveness. The information demonstrates that the subject device is substantially equivalent to the predicate devices.