January 4, 2018

Braemar Manufacturing, LLC
Kent Sayler
VP of RA/QA
3890 Murphy Canyon Road, Suite 100
San Diego, California 92123

Re: K171410
Trade/Device Name: ePatch®
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: December 5, 2017
Received: December 6, 2017

Dear Kent Sayler:

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.

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.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171410

Device Name
ePatch®

Indications for Use *(Describe)*

The ePatch® is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety.

The ePatch® is intended for use by adolescents 18-21 and adults.

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

1. Sponsor

Braemar Manufacturing, LLC
3890 Murphy Canyon Road, Suite 100
San Diego, CA 92123 USA

Contact Person: Kent Sayler
Telephone: 619-243-7560

Date Prepared: May 11, 2017

2. DEVICE NAME

Classification Name: Recorder, Magnetic Tape, Medical

Classification Regulation: 21 CFR 870.2800

Product code: DSH

Trade / Common Name: ePatch®

3. PREDICATE DEVICES

Primary Predicate:

DMS Service LLC myPatch®s- subject of K160704

Secondary Predicate:

DMS Service LLC myPatch® Ambulatory ECG Recorder- subject of K131190

4. DEVICE DESCRIPTION

The ePatch® ECG Recorder is intended for continuous recording of heart action potentials (ECG). While in use, the sensor is connected to a compatible ECG electrode and placed on the patient.

The ePatch® ECG Recorder is a small digital Holter recorder intended for use by professionals to acquire continuous ambulatory recording of heart action potentials (ECG) from a patient through a compatible ECG patch electrode. The ePatch® is intended for use in a clinical, point of care or at a patient setting. The recording time of the ECG recorder is dependent on the set configuration of the recorder (sample rate and channel selection). The patient's ECG is recorded to the ePatch® ECG Recorder and then transferred via the ePatch® USB cable to a Holter analysis system for review by physician or other qualified personnel.

The ePatch® ambulatory electrocardiograph (ECG) recorder is a small, lightweight monitor that records ECG continuously. The unit records 1, 2 or 3 channels of ECG up to 9 days. The device is composed of a large ECG electrode and an ECG recorder. The ECG recorder snaps onto the electrode and records until the recorder is removed from the electrode. At the end of the recording, the recorder can be plugged into a PC via a USB cable. The ECG recording can be transferred in an available file format at can be processed through recording processing software provided by recording processing software manufacturers and analyzed by qualified healthcare providers. The ePatch® can be worn continuously up to 5 days in homes, healthcare facilities, hospitals, and wherever the patient may go. The components that are part of the ePatch® recorder are a lead wire, USB cable and the ePatch® electrode.

During the recording the patient wears the ePatch® connected to an electrode on the upper sternum or an alternative placement on the upper torso. The ePatch® consists of a microprocessor, measuring circuit, memory, data storage, light-emitting diode (trans-illuminates the plastic casing), and contract to the electrode. In addition to that, ePatch® contains firmware to control the collection of the ECG data and software to transfer to the processing software.

The ePatch® components are described below:

Sensor: The sensor has interfaces to a compatible patch and the ePatch® Micro USB cable. The sensor is rechargeable and reusable. The sensor contains internal non-volatile storage that stores the ECG data until it is emptied or, optionally, until the start of a new recording. The sensor also contains embedded software for recording ECG, storing ECG, and charging. When the sensor is connected to a PC through the ePatch® Micro USB cable, the recorded ECG files are accessible as files on an external drive.

The battery is a rechargeable lithium polymer battery with a built-in protection circuit. The charge of the ePatch® is by use of a USB cable which can only be connected to the ePatch® when it is not connected to the electrode. The ePatch® device must be snapped onto the electrode to turn on and acquire data. The ePatch® has a serial number and product number in a bar code format and numbers to secure the traceability of the equipment and the data during and after the investigation. The ePatch® is a reusable device.

Electrode:

The electrode (accessory to ePatch®) consists of one layer of one-sided adhesive tape that runs the full length of the electrode. This adhesive tape allows the electrode to be placed on the upper sternum or torso. The electrode gel is placed on the underneath side of the adhesive tape. Through this electrode gel the ECG of the patient is measured. The top side of the electrode has the connector to the ePatch® and one snap for an optional lead wire. The conductor paths are flex strips that run between the connector and the electrode gel. A release liner is placed on the bottom of the electrode. The release liner covers the adhesive tape and the electrode gel. This liner is torn off when placing the ePatch® on the upper sternum. The electrode has to be connected to the ePatch® to have any practical use. The electrode is a single use device and is disposed of after the one single use.

When recording a 3 channel ECG, a standard lead wire is attached to the snap on the front, bottom of the electrode. This lead wire attaches to any standard ECG electrode. The normal placement of this electrode is the V5 position.

5. INTENDED USE / INDICATIONS FOR USE

The ePatch® is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety.

The ePatch® is intended for use by adolescents 18-21 and adults.

6. TECHNOLOGICAL COMPARISON OF EPATCH® WITH PREDICATE DEVICES

Technical Equivalence	ePatch® Proposed	myPatch®s K160704 Primary Predicate	myPatch K131190 Secondary Predicate
Indications for Use	ePatch® is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. The ePatch® is intended for use by adolescents 18-21 and adults.	myPatch®s is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. The myPatch®s is intended for use by Adults and all Pediatric subgroups.	The myPatch is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, presyncope, syncope, fatigue, chest pain and/or anxiety.
Type of ECG Recorder	Patch	Patch	Patch
Number of ECG Channels	1,2 or 3	1, 2 or 3	1 or 2
Wear Time	Up to 5 days	Up to 7 days	Up to 3 days
Recording Format	Continuous	Continuous	Continuous
Power Requirement	Lithium Polymer Nominal voltage: 3.7V Charging voltage: 4.2V Capacity: Typical 350 mAh	Lithium Polymer Charging voltage: 3.7v Capacity350 mAh	Lithium Polymer Charging voltage: 3.7v Capacity: 250 mAh
Sensor Dimensions	10 x 40 x 49mm	10 x 40 x 49 mm	8.8 x 39.1 x 48mm
Sensor Weight	16 grams	7 grams	15 grams
Frequency Response	0.05-215 Hz	0.05Hz – 110Hz	0.67Hz – 40 Hz
Input Impedance	>10MOhms	>10MOhms	>10MOhms
Resolution	12 bit or 16 bit, depending on customer preference	12 bits	12 bits
Performance Standard	Design Verification IEC 60601-2-47	Design Verification IEC 60601-2-47	Design Verification IEC 60601-2-47
Safety			
	IEC 60601-1 Basic Safety & Essential Performance IEC 60601-2-47 IEC 60601-1-11	IEC 60601-1 Basic Safety & Essential Performance IEC 60601-2-47	IEC 60601-1 Basic Safety & Essential Performance IEC 60601-2-47
Biological Compatibility	ISO 10993-1	ISO 10993-1	ISO 10993-1
Single Use Patch	Reusable/Rechargeable Monitor, Single Use Electrode	Reusable/Rechargeable Monitor, Single Use Electrode	Reusable/Rechargeable Monitor, Single Use Electrode
Recording Standard	Holter	Holter	Holter

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ePatch

Technical Equivalence	ePatch® Proposed	myPatch®s K160704 Primary Predicate	myPatch K131190 Secondary Predicate
Recording Format	Continuous	Continuous	Continuous
Patch Placement	Sternum or appropriate position on torso	Left Sternum	Sternum
Recording Period	Up to 9 days	Up to 7 Days	Up to 3 Days

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The technological characteristics of the proposed ePatch® are very similar to the predicate devices. All of the devices are comprised of essentially identical materials and configurations in that they all consist of a sensor, patch and a USB cable. The design and operational characteristics are identical for the proposed and predicate devices in that they all record ECG up to 9 days (9 days for ePatch® , 7 and 3 days for myPatch/s configurations) on the torso of a patient through a compatible ECG electrode. The proposed and predicate devices provide up to 3 channels with similar weights, frequencies and duration of use. All of these technological characteristics are identical in fit, form and function resulting in the ePatch® being substantially equivalent to the predicate myPatch/s devices.

The operational characteristic of the ePatch® and myPatch/s recorders are identical in that they are all small digital Holter recorder operated by professionals to acquire ECG data from a patient in a clinical, point of care or at a patient setting. The ePatch® ECG Recorder can record ECG up to 9 days on the torso of a patient through the ePatch® compatible ECG electrode (length or recording time is based on the sample rate and channel selection) whereas the predicate myPatch/s devices record from 3-7 days. The patient's ECG results are managed identically for both the ePatch® and the predicate myPatch/s devices in they are recorded to the ECG Recorder and then transferred via USB cable to a Holter analysis system for review by physician or other qualified personnel.

8. PERFORMANCE STANDARDS

The FDA Recognized Standards for which ePatch® ®s conforms to are listed below:

- IEC 60601-1-2:2007 (3rd Edition) Clause 6.1 Emission, Clause 6.2 Immunity Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests FDA Recognition #19-1
- ISO 15223-1:2012 Symbols to be used with medical devices labels, labeling and information supplied FDA Recognition #5-91
- IEC 62304:2006 Software Life Cycle Process FDA Recognition #13-32
- IEC 60601-1-11:2010 Medical Electrical Equipment used in Home Healthcare Environment FDA Recognition #19-6
- IEC 60601-1:2012 Medical Electrical Equipment Part 1-2 General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests FDA Recognition #19-4
- IEC 60601-2-47 Edition 2.0 2012 Ambulatory Electrocardiographic Systems FDA Recognition #3-128
- ANSI/AAMI EC12 “Disposable ECG Electrodes” FDA Recognition #3-52
- ISO 10993-1:2009 Part1, Biological Evaluation of Medical Devices, Evaluation & Testing within a risk management process; FDA Recognition #2-156
- ISO 14971:2007 Applications of Risk Management to Medical Devices FDA Recognition # 5-70
- IEC 62366:2008 Application of Usability Engineering to Medical Devices

9. NON-CLINICAL TESTING SUMMARY

Biocompatibility, electrical safety, electromagnetic compatibility, software verification and validation and usability testing were performed to support the safety and effectiveness of the ePatch® device.

10. CLINICAL TESTING SUMMARY

Braemar Manufacturing Traditional 510(k)
ePatch

Validation of patch adhesion and signal quality data were conducted to support substantial equivalence.

11. SUBSTANTIAL EQUIVALENCE CONCLUSION

The above testing supports that the proposed device is as safe, effective and performs as well as the legally marketed predicate in its intended use. Therefore, the proposed device is substantially equivalent to the predicate.