July 5, 2018

DailyCare Biomedical, Inc
Ming Lee
Management Representative
7f, No. 1, Ding-An Rd, Zhongli Dist.
Taoyuan City, Taoyuan, Taiwan 320

Re: K172778
Trade/Device Name: CheckMyHeart Plus
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: June 5, 2018
Received: June 8, 2018

Dear Ming Lee:

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 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)*
K172778

Device Name
CheckMyHeart Plus

Indications for Use *(Describe)*
CheckMyHeart Plus is intended to record, recall, store and transfer Lead I ECG signals for home health care use. The intended users are adults above 21 years old. This device is not intended to substitute for a hospital diagnostic ECG device. This device is also not intended for recording and transmission of user's ECG signals simultaneously.

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.

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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

This 510 (K) summary is being submitted in accorndance with requirements of Title 21,CFR Section 807.92.

510(K) Number : K172778

1.	**SUBMITTER**	DAILYCARE BIOMEDICAL INC 7f, No. 1, Ding-An Rd, Zhongli Dist. Taoyuan City Taoyuan, TAIWAN (CHINA) 320
	Contact Person:	Joanne Tsai, Regulatory Affairs Engineer Tel: +886-3-263-1168 ext.318 Fax: +886-3-462-7866 E-mail: ctsai@dcbiomed.com
	Date Prepared:	May 18th, 2018
2.	**DEVICE**	Name of Device: CheckMyHeart Plus Common or Usual Name: Electrocardiograph Model Number: CMH 4.0 Classification Name: Electrocardiograph (21 CFR 870.2340) Regulatory Class: II Product Code: DPS Review Panel: Cardiovascular
3.	**PREDICATE DEVICE**	READMYHEART, MODEL RMH3.0, K050620
4.	**DEVICE DESCRIPTION**	CheckMyHeart Plus is intended to record, recall, store and transfer single lead electrocardiographic monitor for recording and displaying real-time ECG data for home health care use. The intended users are adults above 21 years old who might experience transient symptoms that may suggest cardiac conduction abnormity or by adult

users whenever they want to have routine checks. This device is not intended to substitute for a hospital diagnostic ECG device. ECG acquisition and transmission can be voluntarily and mutually activated by the adult users for the purpose of healthcare management and reference for healthcare professionals. This device provides a parameter of heart rate variability (HRV) in RR interval which is only mathematical analysis and is not intended to produce any interpretation of those measurements or any kind of diagnosis.
CheckMyHeart Plus is a handheld, personalized use, dry electrode and affordable ECG recording device that records user's cardiac functions for daily health check. It takes ECG signals of users with thumbs press on electrode at CheckMyHeart Plus gently. The device will record user's ECG signal for 300 seconds, and automatically stores signals into the build-in memory.

Standard accessories:

A. CheckMyHeart Plus Heart rate Variability (HRV) analysis Software CD X 1
B. USB Cable X 1

5. INDICATION FOR USE

CheckMyHeart Plus is intended to record, recall, and store and transfer Lead I ECG signals for home health care use. The intended users are adults above 21 years old. This device is not intended to substitute for a hospital diagnostic ECG device. This device is also not intended for recording and transmission of user’s ECG signals simultaneously.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A.

CheckMyHeart Plus (CMH 4.0)	**READMYHEART (RMH3.0)**	**Similarity**	**Difference**
CheckMyHeart Plus is intended to record, recall, store and transfer single lead electrocardiographic monitor for recording and displaying real-time ECG data for home health care use. The intended users are adults above 21 years old who might experience transient symptoms that may suggest cardiac conduction abnormity or by adult users whenever they want to have routine checks. This device is not intended to substitute for a hospital diagnostic	The device is intended for home use by users who might have transient symptoms that may suggest cardiac conduction abnormity or by users who want to monitor the cardiac function for HOME HEALTH CARE from Lead I ECG signal. ECG acquisition and transmission is voluntary and mutually activated by the user. The intended users are adults above 20 years old. This device is not intended for use as precisely diagnostic	Both CheckMyHeart Plus and READMYHEART are electrocardiographic monitor for recording and displaying real-time ECG data for the purpose of home health care use. The users for CheckMyHeart Plus and READMYHEART can measure the parameter of heart rate variability (HRV) in RR interval. Their target population aims to the adults above 20 years old who might experience cardiac conduction	Originally, READMYHEART can only let users to see the outcome of measurement on the computer with proper software installation. CheckMyHeart Plus is basically an upgrade model of READMYHEART. The upgrade feature in CheckMyHeart is to show the user real-time signal output on the screen of the device.

ECG device. ECG acquisition and transmission can be voluntarily and mutually activated by the adult users for the purpose of healthcare management and reference for healthcare professionals. This device provides a parameter of heart rate variability (HRV) in RR interval which is only mathematical analysis and is not intended to produce any interpretation of those measurements or any kind of diagnosis.	tool. This device is also not intended for recording and transmission of user's ECG signal simultaneously. This device provides a parameter of heart rate variability (HRV) in RR interval which is only mathematical analysis and is not intended to produce any interpretation of those measurements or any kind of diagnosis. The device detects the appearance of irregular heart beat (IHB) during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected. Users with implanted pacemaker are not	abnormity or by adult users whenever they want to have routine checks. They both are not intended to substitute for a hospital diagnostic ECG device. All the materials, components, energy source and features are the same in CheckMyHeart Plus and READMYHEART	

	recommended to use this device.		

B. Technological Characteristics

Item	CheckMyHeart Plus (CMH 4.0)	READMYHEART (RMH3.0)	Similarity	Difference
Input impedance	> 20 M Ohm	> 10M Ohm		Yes
Input dynamic range	+/- 3 mV	+/- 2 mV		Yes
Bandwidth	0.1 – 40 Hz	0.15 ~ 40 Hz	Yes	
CMRR (Common Mode Rejection Ratio)	> 95 dB	> 60 dB		Yes
A/D conversion	12 bits	12 bits	Yes	
Sampling Rate	250 samples/sec	250 samples/sec	Yes	
Measurement Time	300 seconds	300seconds	Yes	
Display	240×128 Dot-matrix LCD display	LCD display panel	Yes	
Input	Dry conduction electrodes	Dry conduction electrodes and/or external auxiliary electrodes and conductive adhesive ECG pads	Yes	
Output	USB interface	USB interface	Yes	
Power Supply	1.5V (AAA) x 2	1.5V	Yes	

		(AAA) x 2		
Product Size	124 × 78 × 24 mm	120 × 80 × 20 mm		Yes
Weight	150 g excluding batteries	116g excluding batteries		Yes
Environnemental Conditions				
Storage temperature	-4°F~122°F (-20°C~ 50°C)	-4°F~122°F (-20°C~ 50°C)	Yes	
Operating temperature	50°F~104°F (10°C ~ 40°C)	50°F~104°F (10°C ~ 40°C)	Yes	
Humidity	25% ~ 95%	25% ~ 95%	Yes	
Measurement Range				
Average Heart Rate	45 to 180 bpm	45 to 180 bpm	Yes	

The upgrade specifications in CheckMyHeart Plus are to enhance the quality of signals during the measurement as well as the upgrade improves the data presentation to the users. The difference of CheckMyHeart Plus and READMYHEART do not raise new concern on safety and efficacy.

C. Safety

No	Name of Test	Standard	**CheckMyHeart Plus (CMH 4.0)**	**READMY HEART (RMH3.0)**
1	Radiated Emission Measurement	EN55011 :2009+A1:2010 Class B	Pass	Pass
2	Electrostatic Discharge Immunity Test(ESD)	EN61000-4-2 :2009 EN60601-1-2 :2015	Pass	Pass
3	Radiated	EN61000-4-3 :2006+A2:2010	Pass	Pass

	Susceptibility Measurement(RS)	EN60601-1-2:2015		
4	Power Frequency Magnetic Field(Magnetic)	EN61000-4-8:2010 EN60601-1-2:2015	Pass	Pass
5	Biocompatible evaluation	ISO 10993-1:2009/AC:2010	Pass	Pass

The safety tests of CheckMyHeart Plus and READMYHEART had been evaluated according to the same standards and the results of both devices passed the criteria.

D. Performance Characteristics

No.	Name of Test	Standard	**CheckMyHeart Plus (CMH 4.0)**	**READMY HEART (RMH3.0)**
1	Indication of inoperable ELECTROCARDIOGRAPH	IEC60601-2-25:2011	Pass	Pass
2	Goldberger and Wilson LEADS	IEC60601-2-25:2011	Pass	Pass
3	Input impedance	IEC60601-2-25:2011	Pass	Pass
4	COMMON MODE REJECTION	IEC60601-2-25:2011	Pass	Pass
5	Overload tolerance	IEC60601-2-25:2011	Pass	Pass
6	Baseline(Noise Level)	IEC60601-2-25:2011	Pass	Pass
7	Frequency response(HF)-A	IEC60601-2-25:2011	Pass	Pass
8	Low	IEC60601-2-25:2011	Pass	Pass

	frequency(impulse) response			
9	Linearity and dynamic range	IEC60601-2-25:2011	Pass	Pass
10	Recording Speed	IEC60601-2-25:2011	Pass	Pass

CheckMyHeart Plus and READMYHEART passed the same performance tests according to the same design of tests from the standards listed above. Both CheckMyHeart Plus and READMYHEART have shown the same efficacy.

7. **PERFORMANCE DATA**

The following performance data were provided in support of the substantial equivalence determination.

A. Biocompatibility

CheckMyHeart Plus and READMYHEART have the same product design and technologies. The materials provided by the suppliers as well as the materials' compositions do not change. The incoming, in-process and final quality inspections all follow the same procedures. Overall, the production and inspection process control remains the same, which do not raise any biocompatibility risks.

B. Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC tests were conducted on CheckMyHeart Plus and READMYHEART. CheckMyHeart Plus and READMYHEART complies with IEC 60601-1:2005/A1:2012, EN60601-1:2006/AC:2010 and EN60601-1:2006/A1:2013.

C. Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator. The software is an accessory to CheckMyHeart Plus that has Moderate Level of Concern.

D. Standards complied

a. IEC 60601-2-25: 2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs (Edition 2.0, 3-105)
b. ISO 10993-1: 2009 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)] (Fourth Edition 2009-10-15, 2-220)
c. EN 60601-1:2006+ A1:2013 Medical electrical equipment - Part 1: General requirement for safety
d. IEC 60601-1:2005+AMD1:2012 CSV Consolidated version Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
e. IEC 60601-1-2:2007 Medical electrical

equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests (Edition 3, 19-1)

f. ISO 14971: 2007 Medical Devices – Application of Risk Analysis Management to medical device. (Second Edition, 5-40)

8. **CONCLUSIONS** CheckMyHeart Plus and READMYHEART both are intended to provide user to monitor Lead I ECG signal and parameter of heart rate variability (HRV). Their technologies are similar and there is no extra concern and risks on safety and efficacy. The safety and efficacy tests on CheckMyHeart Plus and READMYHEART have demonstrated the same results.

In conclusion, the results drawing from tests, validation and risk analysis, CheckMyHeart Plus and READMYHEART are the substantial equivalent.