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JUL 14 2005

DailyCare BioMedical ReadMyHeart (Model RMH 3.0) Premarket Notification

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1.0 Submitter's Indentification:

Submitter's Name:	DailyCare BioMedical Inc.
Address:	8F, 25-3, Ji-Lin Road, Chungli 320, Taiwan
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Contact:	Mr. Daniel J. H. Chang

2.0 Device Name:

Trade Name:	ReadMyHeart - Model RMH3.0
Common Name:	Handheld ECG monitor
Classification Name:	Electrocardiograph (per 21 CFR 870.2340)

3.0 Classification: Class II

4.0 Predicate Device: This predicate device is ReadMyHeart (RMH2.0, k042814) marketed by DailyCare BioMedical Inc.

5.0 Intended Use:

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 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 recommended to use this device.

6.0 Device Description:

ReadMyHeart 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 ReadMyHeart gently. The device will record user's ECG signal for 30 seconds, and automatically stores the last 15 seconds signals into the build-in memory, while three parameters measured, mainly, Heart Rate (HR), ST segment and QRS interval of cardiac ECG signal, displays on LCD of the device.

The device also detects the appearance of irregular heart beat (IHB) during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

This device provides a parameter of heart rate variability (HRV) in RR interval which is only mathematical analysis when recording the signal for 180 seconds. The HRV is not intended to produce any interpretation of those measurements or any kind of diagnosis.

User may also record ECG signals optionally through auxiliary external electrode provided separately, if thumb pressings are inconvenient for any reason. The data stored in the memory can be transferred to Personal Computer via USB. With friendly GUI software provided separately, data stored in ReadMyHeart can be printed for analysis, and for long-term tracking. ReadMyHeart is powered by internal battery source. Users may activate the device to acquire ECG Lead I information voluntarily and mutually.

Furthermore, ReadMyHeart (Model RMH3.0) is modified and has generally the same design from DailyCare BioMedical Inc.'s prior device – ReadMyHeart (RMH2.0, K042814).

7.0 Performance Summary:

In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards include

* All Safety test according to IEC 60601-2-25 & IEC 60601-1,
* EMC tests according to IEC 60601-1-2
* Performance tests according to IEC 60601-2-47 and IEC 60601-2-51 voluntarily.
* Environment tests are tested to comply with the safety requirements.

Furthermore, the performance is tested with MIT-IBH database and simulators and meets the requirements.

8.0 Discussion of Clinical Test performed:

Since the ECG parameters algorithm and hardware design in this device is exactly the same as in the predicate device, ReadMyHeart (RMH2.0, K042814), no clinical validation for ECG parameters is required. Instead, we conducted a simulator and MIT database comparison study for the function of irregular heartbeat detection. Furthermore, HRV is only the mathematical analysis of heart beat and is not shown safe and effectiveness and has not been approved by FDA for a specific clinical diagnosis in any devices, so that is for reference only, therefore, no clinical validation is required for HRV.

9.0 Conclusions:

ReadMyHeart (Model RMH3.0) is a modification from predicate device ReadMyHeart (RMH2.0, K042814). It has generally the same technological characteristics and intended use. Moreover, bench testing contained in this submission supplied demonstrates that any differences in their technological characteristics do not raise and new questions of safety or effectiveness. Thus, the ReadMyHeart (Model RMH 3.0) is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2005

Dailycare Biomedical, Inc.
c/o Mr. Daniel J. H. Chang
Senior Engineer
8F, 25-3, Ji-Lin Road
Chungli 320
TAIWAN

Re: K050620
ReadMyHeart model RMH 3.0
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: June 29, 2005
Received: June 29, 2005

Dear Mr. Chang:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Brian D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050620

Device Name: ReadMyHeart – Model RMH3.0

(DailyCare BioMedical Inc.)

Indications for Use:

The device is a personal single lead Electrocardiograph monitor for home health care use. The device is intended for self-testing by users who might experience transient symptoms that may suggest cardiac conduction abnormity or by users whenever desired as routine recordings for daily home health care from Lead I ECG signal. ECG acquisition and transmission is voluntary and mutually activated by the user and the intended users are adults above 20 years old.

The user is normally not required to apply electrode on body. Two electrodes integrated within the device are provided. The user has to press his/her thumbs on the electrodes in order to record the ECG signal. The users may also record the signals optionally through auxiliary external electrode provided separately if thumb pressing is not convenient for reason. It is highly recommended to use auxiliary external electrode for HRV analysis.

The recorded data can be downloaded to Personal Computer via USB interface port. This device is not intended for use as precisely diagnostic tool. This device is also not intended for recording and transmission of user's ECG signal simultaneously. Users with implanted pacemaker are not recommended to use this device.

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.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050620