K042814

JAN - 6 2005

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 Name: DailyCare BioMedical Inc.

Address: 8F, 25-3, Ji-Lin Road, Chungli 320, Taiwan

Tel: +886-3-2621688

Fax: +886-3-2617688

Contact: Mr. Jen-Hao Chang

E-Mail: info@dcbiomed. com

2.0 Device Name

Trade Name: ReadMyHeart

Common Name: Handheld ECG monitor

Classification name: Electrocardiograph

3.0 Classification: Class II

4.0 Predicate Device: The predicate device is the **ecg@home**(K012012) marketed by H&C MEDICAL DEVICES SPA.

5.0 Intended Use: ReadMyHeart is intended for use by users who have transient symptoms that may suggest cardiac conduction abnormalities 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 also not intended for recording and transmission of user's ECG signal simultaneously.

This device is not intended for use as precisely diagnostic tool.

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 user/patient 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. 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 has similar general design with ecg@home(K012012) marketed by H&C MEDICAL DEVICES SPA.

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

Furthermore, A comparison study with a hospital use common electrocardiograph recorder was performed in order to validate the performance of ReadMyHeart.

The comparison study demonstrated that the recordings performed on the subjects using ReadMyHeart is highly comparable to those obtained with the hospital use common electrocardiograph recorder.

8. Conclusions:

ReadMyHeart have the same intended use and similar technological characteristics as **ecg@home(K012012)** marketed by H&C MEDICAL DEVICES SPA.. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise and new questions of safety or effectiveness. Thus, the **ReadMyHeart** 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

JAN - 6 2005

DailyCare BioMedical Inc.
c/o Ms. Jennifer Reich
Harvest Consulting Corp.
3892 South America West Trail
Flagstaff, AZ 86001

Re: K042814
Trade Name: ReadMyHeart
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: October 8, 2004
Received: October 12, 2004

Dear Ms. Reich:

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 (301) 594-4646. 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,

Bram 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): K042814

Device Name: **ReadMyHeart**
DailyCare BioMedical Inc.

Indications For Use:

The device is a personal single lead Electrocardiograph monitor. The device is intended for self-testing by patients by recording 15 seconds of the first standard lead I of Electrocardiogram. The recording is activated by the patient when symptoms are experienced or whenever desired as routine recordings to be analyzed by a trained physician. The intended user are Users who are above 20 years old.

The user is normally not required to apply electrode on the body. Two electrodes integrated within the device are provided. The user has to press his thumbs on the two electrodes in order record the ECG signal.

The User may also record ECG signals optionally through auxiliary external electrode provided separately, if thumb pressings are inconvenient for any reason.

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.

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K042814
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number