

JUL 15 2011

510(k) Summary

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

1.0 submitter's information

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 Contact: Liu Yi
 Date of Application: 12/11/2010

2.0 Device information

Device name: ACG-8511 series Portable ECG Monitor
 Model No: ACG-8511 (X =A~Z, Y= blank or A~Z)
 < Deciding When to Submit a 510(k) for a Change to an Existing Device >

3.0 Classification

Production code: DPS- Eelectrocardiograph
 Regulation number: 21 CFR 870.2340
 Classification: II
 Panel: Cardiovascular

4.0 Predict device information

1	Manufacturer: Omron Healthcare, Inc Device: HCG-801 portable ECG Monitor 510(k) number: K060766
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5.0 Intended use

ACG-8511 is a kind of user-activated ECG event recorder. It allows user to initiate an ECG recording when he or she experiences symptoms such as heart pain, palpitations and shortness of breath. These symptoms are transient and difficult to be recorded by conventional devices. The measurements recorded by an ECG monitor, when combined with a medical examination, can help your doctor monitor your heart condition. The ECG measurements recorded by the unit are NOT designed or intended for medical diagnosis.

The intended use and the indication for use of ACG-8511, as described in its labeling are the same as the predict device HCG-801.

6.0 Device description

The Portable ECG monitor, ACG-8511, is able to measure the electrical impulse as it passes across and through the heart. And give an indication to the user on the LCD which contains the heart rate and the rhythm of the heart.

The user can operate the monitor according to the indication provided by the menus displayed on the LCD. Each record contains about 30s ECG data.

The ACG-8511 Portable ECG Monitor is activated by the user whenever symptoms, such as heart pain, palpitations and shortness of breath are experienced. The recorded data will then be shown to physicians or other health care professionals for confirmation of these symptoms as reliable evidence.

ACG-8511 is a portable ECG monitor used for self-testing before diagnosis and are not recommended for users with implanted pacemakers. It works with dry single lead, and has 3 testing mode:

a) Hand to chest mode, using the metal electrodes integrated on the device. Place your right thumb on the right two electrodes of the device and place the chest electrode on bare skin about 5cm below your left nipple.

b) Two hands mode, using the metal electrodes integrated on the device. Place your right thumb on the right two electrodes, and the left big thenar on the left electrode.

c) Lead wires modes, using lead wires and three disposable electrodes. Paste the disposable electrodes on your body and connect them to the device through a 3 wire cable.

The measurement data can be recorded on the SD card, then download to PC after the measure process is completed.

7.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	Comparison result
Design principle	Identical
Performance	Similar
Biocompatibility	Identical
Mechanical safety	Identical
Energy source	Identical
Standards met	Identical
Electrical safety	Identical
EMC	Identical
Function	Similar

8.0 Performance summary

Testing for ACG-8511 Portable ECG Monitor have been tested to meet all of the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).
- ANSI/AAMI EC38, Medical electrical equipment—Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems, 2007.
- ISO 10993-1:2002: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-10:2002/Amd1:2006: Biological Evaluation of Medical Devices-Part 10: Tests for irritation and delayed-type hypersensitivity.
- ISO 10993-12:2002: Biological Evaluation of Medical Devices-Part 12: Sample preparation and reference materials.

9.0 Comparison to the predict device and the conclusion

Our device ACG-8511 Portable ECG Monitor is substantially equivalent to the Portable ECG Monitor HCG-801 whose 510(k) number is K060766.

The ACG-8511 is very similar with the predicted devices in the intended use, the design principle, the energy source and the applicable standards.

However, appropriate test will be conducted and specified acceptance criteria will be met before ACG-8511 is marketed.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

JUL 15 2011

Andon Health Co., Ltd.
c/o Mr. Liu Yi
President
No. 3 Jin Ping Street, Ya An Road, Nankai District
Tianjin
China 300190

Re: K110328
Trade/Device Name: ACG-8511 Portable ECG Monitor
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: DPS
Dated: June 19, 2011
Received: June 21, 2011

Dear Mr. Yi:

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 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.

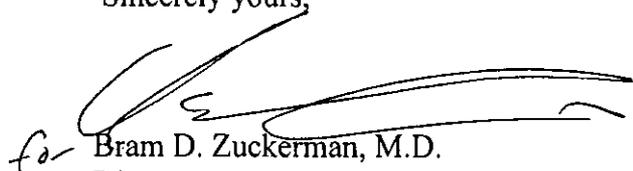
Page 2 – Mr. Liu Yi

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

Statement of Indications for Use

510(k) Number : _____

Device name: ACG-8511 Portable ECG Monitor

Indications for use:

The ACG-8511 portable ECG Monitor is intended for recording and displaying ECG data by adult patients who are concerned about their heart rhythm. This ACG-8511 portable ECG Monitor allows the consumer to record their ECG data into the device memory for display by healthcare professionals during office visits.

Specifically, ACG-8511 portable ECG Monitor is intended for adult patients who are concerned about their heart rhythm or have experienced the following symptoms that are suggestive of abnormal heart rhythm:

- Skipped beats
- Pounding heart (palpitations)
- History of arrhythmia

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110328

Page 1 of 1