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510 (k) Summary SEP 12 2011

K 111438

In accordance with 21 CFR 807.87(h), the following 510 (k) summary has been prepared per 21 CFR 807.92.

Electrocardiograph Recorder / ECG Monitor

Submitter: REKA Pte. Ltd
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Email: Larrypetersen7@gmail.com
Date summary prepared: July 29, 2011
Device trade name: REKA E100
Device common name: ECG Event Recorder (Cardiac Rhythm Monitor)
Device classification: Handheld ECG Recorder /Monitor; Product Code: DPS
21 CFR 870-2340, Class II

Legally marketed Predicate devices to which this device is Substantially Equivalent:

Predicate Device #1 **Daily Care Biomedical, Inc.** Model: **ReadMyHeart**
FDA 510(k): **K052303** (2005)

Predicate Device #2 **Omron Corp.** Model: **HCG- 801**
FDA 510(k): **K060766** (2006)

Predicate Device #3 **Card Guard Scientific Survival, Ltd.** Model: **CG-6106**
FDA 510(k): **K963811** (1996)

Predicate Device #4 **Beijing Choice Electronics** Model: **MD100**
FDA 510(k): **K093872** (2010)

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Description of the Device: Section 5

The REKA E100 device has the following characteristics:

Device Description

The REKA E100 ECG Event Recorder (Cardiac Rhythm Monitor) is designed for on-demand, self-recording of a single channel ECG by patients at almost any place and any time. The recording takes 30 seconds and is transmitted to backend website for analysis and interpretation by medical professionals of the remote Monitoring Center. ECG signals are acquired by the two (2) built-in finger electrode sensors on the device. As an alternative, a better quality ECG can be recorded using the 2-leadwire cable with 2 electrodes pasted on body. The acquired signals are recorded in a build-in NAND flash memory and E100 can store up to 4000 ECG records.

The recorded EGG data can be transferred to mobile phone using micro USB cable/ 30-pin cable provided. The ECG then can be transmitted via cellular link or WiFi to an Internet depository when the patient ECG records are filed. The Internet depositories compatible with E100 can be accessed via www.reka.net and www.rekahealth.com. The compatible smart cell/mobile phones that can upload ECG records from E100 include iPhone®, Blackberry®, Symbian® and smart phones running on Android™. These mobile phones will require to install E100 Uploader (Apps) developed by REKA, the user can easily download the Apps from App World, Android Market etc. and install it.

Alternatively, the EGG signals stored in E100 can be transmitted to backend website through PC or Laptop with Internet connection by plugging E100 to computer using USB cable. For computer with Windows® & Mac®, user can easily access to the corresponding Uploader apps pre-stored in the device to run it for installation at 1st time use. After then the Uploader runs automatically once E100 is plugged in. For computer with Linux®, user can directly upload ECG data by clicking the apps, no installation required.

Indications for Use:

The REKA E100 ECG Event Recorder (Cardiac Rhythm Monitor) is intended for use by patients who may experience transient symptoms that could suggest cardiac arrhythmia. The device records the patients EGG on demand at any time the patient feels any physical symptom indicative of a potential heart event. A 30 second single channel ECG is recorded and transmitted to a monitoring center. The monitoring center provides the EGG data to the medical practitioner for evaluation. The Indications for Use are the same as the predicate devices.

The REKA E100 is designed for self-recording an ECG by out-hospital patients and for analysis by medical professionals at a remote monitoring center or a cardiologist or a physician. The E100 EGG is intended for use by patients who may experience transient symptoms that could suggest cardiac arrhythmia. The device is intended for non-lethal long term monitoring. The intended use is the same as the predicate devices.

It is suitable for adult users, who suffer from cardio-vascular diseases, are considered at high risk for potential cardiovascular events or other adult people who are concerned about their heart function and rhythm as they more about during their daily life. This device is not intended for use as a conventional diagnostic tool, but is to be used as a healthcare patient evaluation

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tool which can provide a doctor with the recorded ECG data as a reference to help detect and analyze heart events that a patient may experience at any time or any place.

Summary of Technological Characteristics & Principals of Operation

The technological characteristics and principles of operation of REKA E100 are the same as the predicate device. The two finger electrode sensors built in the REKA E100 are used for the ECG signal acquisition and the acquired signal is recorded in a build-in memory. Alternatively, patient can use the 2-leadwire cable provided and 2 electrodes pasted on body to capture better quality ECG signal. The ECG data stored in E100 will be transmitted to backend website through smart mobile phone or computer using cables provided. The ECG data uploaded on website will be as reference for analysis by medical professionals at a remote monitoring center or a cardiologist or a physician.

Non-Clinical Performance Tests and Data for the REKA E100:

REKA E100 has been subjected to extensive verification & validation testing.
Final testing of the system included various performance tests and software validation tests designed to ensure that the device meet all of its functional and performance requirements and is fit for its intended use. The following list summarizes the testing performed on the device;

- Product Specification Verification
- Software Verification and Validation according to IEC 60601-1-4 and IEC 62304, including Firmware, Uploader, Backend, and the system level
- IEC 60601-1 Safety Test
- IEC 60601-1-2 EMC Test
- ISO 10993 Biocompatibility Test
- Functionality Test, including accuracy test, compatibility test
- Reliability Test, including drop test, environment test, connector test, button test, packaging test
- Risk Management according to ISO 14971
- Bench Test against predicate device
- Performance Test voluntarily against AAMI EC38

Performance Standards:

This 510(k) submission was written in accordance with the FDA Guidance document "Class II Special Controls Guidance Document: Arrhythmia Detector, October 28, 2003" and the device conforms to the applicable performance requirements contained in and referenced in this document. In addition, this submission was prepared in accordance with "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005".

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Below is the list of the specific recognized standards that Reka E100 conforms to.

1. **IEC 60601-1:1988/A1:1991/A2:1995** Medical electrical equipment – Part 1: General requirements for safety
2. **IEC 60601-1-2:2007** Medical electrical equipment, Part 1-2 General requirements for safety – Collateral Standard: Electromagnetic compatibility -Requirements and tests
3. **ISO 10993-1:2009** Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
4. **ISO 10993-5:2009** Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
5. **ISO 10993-10:2010** Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
6. **IEC 60601-1-4:1996/A1:1999** Medical electrical equipment; Part 1-4 General requirements for safety – Collateral Standard: Programmable electric medical systems
7. **IEC 62304:2006** Medical device software - Software life cycle processes
8. **ISO 15223-1:2007** Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements
9. **ISO 14971:2009** Medical devices -- Application of risk management to medical devices

E100 is also tested voluntarily against the applicable clauses of:

- **AAMI/ANSI EC38:2007** Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

Substantial Equivalence:
The REKA E100 device is substantially equivalent with respect to the indications for use, technological characteristics and performance characteristics to the identified legally marketed predicate devices.

Assessment of non-clinical performance data:
The results of the bench tests (Please refer to Section 18) demonstrate that the REKA E100 is as safe and effective as compared to the currently marketed predicate device.

Summary:
The REKA E100 ECG Monitor has the same intended use as the predicate devices. Based on the assessment of non-clinical performance data to verify the intended use, and the technological characteristic comparison, the REKA E100 is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

REKA Pte, Ltd.
c/o Mr. Larry Petersen
Regulatory Affairs Consultant
1001 Bear Island Road, Suite 136
Summerville, SC 29483

SEP 12 2011

Re: K111438
Trade/Device Name: REKA E100
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: August 9, 2011
Received: August 11, 2011

Dear Mr. Petersen:

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.

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/ucm115809.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

K111438

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Indications for Use

Section 4

510(k) Number: K111438

Device Name: Reka E100

Indications for Use

The REKA E100 EGG Event Recorder (Cardiac Rhythm Monitor) is intended for use by patients who may be at risk for experiencing transient cardiac symptoms that could suggest cardiac arrhythmia. The device records the patients EGG on demand at any time the patient feels any physical symptoms indicative of a potential heart event. A 30 second single channel ECG is recorded and transmitted to a monitoring center. The monitoring center provides the EGG data to the medical practitioner for evaluation. The Indications for Use are the same as the predicate devices.

The device is a handheld, personal electrocardiograph unit, which can measure electrical activities of the heart easily and conveniently. It is immediately available at any time to manually record transient cardiac events, suitable for home health care use, and which can record and store an ECG signal, and then transmit the ECG recording to a hospital or cardiology center for interpretation and review.

It is suitable for adult users, who suffer from cardio-vascular diseases, are considered at high risk for potential cardiovascular events or other adult people who are concerned about their heart function and rhythm as they move about during their daily life.

This device is not intended for use as a conventional diagnostic tool, but is to be used as a healthcare patient evaluation tool which can provide a doctor with the recorded ECG data as a reference to help detect and analyze heart events that a patient may experience at any time or any place.

Prescription Use: X AND/OR Over-The Counter Use: _____

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

Please do not write below this line

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K111438