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510(k) Summary

Parama-Tech Co., Ltd.
Palm ECG Recorder ™, Model EP-201C/202C

1 Ocotober 2006

JUN 29 2007

Sponsor	**Consultant**
Parama-Tech Co., Ltd.	Mr. Richard Keen
2-19-8 Sharyo Higashi-ku	Compliance Consultants
Fukuoka-shi, Japan	1151 Hope Street
Voice 011 81 92-623-0813	Stamford, CT 06907-1659
Fax 011 81 92-623-0814	203 329 2700 F 203 329 2345
s.koga@Parama-Tech Co., Ltd..com	rkeen@fda-complianceconsultants.com
Proprietary Name:	Palm ECG Recorder ™, Model EP-201C/202C
Regulation Number	21 CFR part 870.2340
Product Code	DPS
Classification Name:	electrocardiograph
Device Classification	Class II
Common Name	ECG monitor
Predicate Device	1) Read My Heart K 042814, handheld ECG device 2) OMRON portable ECG Monitor, HCG-801 (K060766)

Device Description

The ***Palm ECG Recorder ™, Model EP-201C/202C***, is made by ***Parama-Tech Co., Ltd.*** This wireless ECG Monitor is portable, non-invasive and handheld. This is a Class II device that measures and displays EGC waveforms, R-R graph, an average heart rate along with comments. Once this device is prescribed by a physician, the ***Palm ECG Recorder ™***, can be used anytime, anywhere by anyone. This devices allows acquisition and transmission of ECG data from the user to a personal computer.

This device is suitable to detect transient symptoms that may suggest abnormal cardiac conditions to monitor cardiac conditions on a daily basis. This device is ideally suited for health care.

Intended Use

This is a screening device intended to capture, display and store transient symptoms that suggest abnormal cardiac condition or to document cardiac conditions. In addition, further interpretation of ECG data recorded by Palm ECG Recorder can be sent to the prescribing physician. The ***Palm ECG Recorder ™ Model EP-201C/202C*** is not a diagnostic or analytic device. It is used for screening purpose only. This is a prescription device for use only under the direction of a physician.

Technological Characteristics and Substantial Equivalence

This device uses electrodes to detect voltages emitted by the body. The calibration is established by the factory and yields accurate and calibrated signals that can maintain calibration over its useful life. The ***Palm ECG Recorder ™, Model EP-201C/202C***, Palm ECG Recorder has benefited from design, development, testing and production procedures that conform to Quality Systems.

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510(k) Summary

Parama-Tech Co., Ltd. has determined that the ***Palm ECG Recorder [tm], Model EP-201C/202C*** is substantially equivalent to

- the *Read my Heart*, Daily Care BioMedical, K042814 which is a Lead I, electrocardiograph monitor and
- the OMRON portable ECG Monitor, HCG-801 (K060766).

Performance Testing

Information submitted in this premarket notification for the ***Palm ECG Recorder [tm], Model EP-201C/202C*** includes results of testing for electrical safety, EMI/EMC, temperature measurement accuracy and results of clinical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

Parama-Tech Co., Ltd.
c/o Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, CT 06907-1659

Re: K061123
Palm ECG Recorder ™, Model EP-201C/202C
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: June 07, 2007
Received: June 07, 2007

Dear Mr. Keen:

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) 276-0120. 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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachner

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

Enclosure

K061123/S2

Indications for Use

510(K) Number (If known): ___K061123_____

Device Name: ***Palm ECG Recorder*** [tm] ***Model EP-201C/202C***

Indications for Use:

The ***Palm ECG Recorder*** [tm] ***Model EP-201C/202C*** is intended for self-testing and home health care use. The ***Palm ECG Recorder*** [tm] ***Model EP-201C/202C*** records, stores and transfers ECG waveforms, R-R graph and average heart rate data and presents these cardiological events in a synchronized time scale for interpretation by a physician trained in such an analysis. This is a prescription device for use only under the direction of a physician. A software user interface allows viewing. This screening tool is not intended for use as a diagnostic tool or as a substitute for a hospital diagnostic ECG device. This device is not intended for simultaneously recording and transmission of a user's ECG signal. This device is not recommended for use with implanted pacemakers.

Prescription Use __XXX_____
(Part 21 CFR 801 Subpart D)

AND/OR

Over - The - Counter Use _____
(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) Donna R. Vorhees

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061123