K103077

# 510(K) SUMMARY

JUL 13 2011

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: Meridian Dynamics Biomedical, Inc. (MD Biomedical, Inc.)

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| 2.0 Device Name | |
| Trade Name: | **Vion® ECG Pen(Model no.: 800E)** |
| Common Name: | Handheld ECG monitor |
| Classification name: | Electrocardiograph |
| 3.0 Classification: | Class II |
| Product Code: | DPS |
| Regulation No.: | 21CFR870.2340 |
| 4.0 Predicate Device: | The predicate device is the Omron HCG-801 portable ECG Monitor (K060766) marketed by Omron Healthcare, Inc. & MD100 Handheld ECG Monitor (K080933) marketed by Beijing Choice Electronic Technology Co., Ltd.. |
| 5.0 Intended Use: | The Vion.ECG Pen **(Model no.: 800E)** is intended for recording ECG data and displaying general information by adult patients who are concerned their heart rhythm and waveform. This Vion.ECG Pen allows the patients to record transient cardiac events voluntarily for providing to the healthcare professionals as references during office visits.<br><br>In addition, the patient can also record their ECG data and transmit the recorded data to personal computer.<br><br>The Vion.ECG Pen is not intended for recording and transmission of user's ECG signal simultaneously. Users with implanted pacemakers are not recommended to use this |

device. This device is not intended to substitute a conventional diagnostic tool.

6.0 Device Description: The MD's Vion.800E ECG Pen is a small, portable and easy-to-use electrocardiograph unit that can record and store electrocardiogram (ECG) measurements of your heart rhythm. Each ECG reading records 30 seconds measurement and these ECG readings can help your doctor monitor your condition.

The unit included build-in memory that can store up to 99 measurements, including the ECG data along with date and time of measurement. With USB interface, it allows you or your doctor to view detail information of measurement.

Furthermore, **Vion® ECG Pen** (Model no.: 800E) has similar general design with the Omron HCG-801 portable ECG Monitor (K060766 ) marketed by Omron Healthcare, Inc.. & **MD100 Handheld ECG Monitor (K080933)** marketed by Beijing Choice Electronic Technology Co., Ltd.

7.0 Non-Clinical Performance Tests 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 test: according to IEC 60601-1-2
- Performance test: according to IEC 60601-2-47

8.0 Clinical test Summary: A Clinical Investigation study was performed in such a way that compared the performance , including Heart rate. QRS interval, QT interval, PR interval, R-wave, S-wave, T-wave -------etc., between single channel patient-activated ECG device "Vion.800E" VS. 12-lead standard ECG "PHILIPS, PageWriter Trim II Cardiograph. 206 patients are involved in this study.

According to the clinical investigation results and discussion, the performance of Vion.ECG Pen (Model: Vion.800E) is as

good as the 12-lead ECG (PHILIPS, PageWriter Trim II Cardiograph) in recording ECG data and displaying general information.

The patient-activated ECG system used in this study is a leadless recorder, which records 30 seconds ECG signal. The time it costs for use is much shorter than other conventional ECG recorders, and requires no external wires and electrodes. Therefore, the patient-activated ECG recorder, Vion.800E, is ideal to be used to document the behavior of rhythm and signal waveform during symptoms in order to replace a more expensive and invasive diagnostic procedures.

**Conclusions:**

Vion® ECG Pen (Model no.: 800E) has the same intended use, principles of operation, and similar technological characteristics as predicate devices. Moreover, bench testing contained in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **Vion® ECG Pen (Model no.: 800E)** is substantially equivalent to the predicate devices.

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

Meridian Dynamics Biomedical, Inc.
C/O Jennifer Reich
Harvest Consulting Corp.
2904 N. Boldt Drive
Flagstaff, AZ 86001

JUL 13 2011

Re: K103077
Trade/Device Name: ECG Pen
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: June 14, 2011
Received: June 24, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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,

for 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): K103077

Device Name: Vion.® 800E ECG Pen
MD Biomedical, Inc.

Indications for Use:

The Vion.ECG Pen **(Model no.: 800E)** is intended for recording ECG data and displaying general information by adult patients who are concerned their heart rhythm and waveform. This Vion.ECG Pen allows the patients to record transient cardiac events voluntarily for providing to the healthcare professionals as references during office visits.

In addition, the patient can also record their ECG data and transmit the recorded data to personal computer.

The Vion.ECG Pen is not intended for recording and transmission of user's ECG signal simultaneously. Users with implanted pacemakers are not recommended to use this device. This device is not intended to substitute a conventional diagnostic tool.

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)

(Division Sign-Off)
Division of Cardiovascular Devices



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