DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

September 19, 2014

Infobionic, Inc.
% Carrie Neuberger
Regulatory Consultant
600 Suffolk Street
P.O. Box 9719
Lowell, Massachusetts 01853

Re: K133753
Trade/Device Name: Mome Ecg Continuous Detection And Arrhythmia Detector
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including St-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: DSI, MLO
Dated: August 11, 2014
Received: August 13, 2014

Dear Carrie Neuberger,

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 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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

Indications for Use

510(k) Number (if known): K133753

Device Name: MoMe™ Continuous ECG Monitor and Arrhythmia Detector System

Indications for Use:

The MoMe™ Continuous ECG Monitor and Arrhythmia Detector System (MoMe™ System) is indicated for:

1. Patients who have demonstrated a need for cardiac monitoring and are at low risk of developing primary ventricular fibrillation or sustained ventricular tachycardia.
2. Patients with dizziness or lightheadedness.
3. Patients with palpitations.
4. Patients with syncope of unknown etiology.
5. Patients who require monitoring for non-life threatening arrhythmias, such as atrial fibrillation, other supraventricular arrhythmias, evaluation of various bradyarrhythmias and intermittent bundle branch block.
6. Patients recovering from coronary artery bypass graft (CABG) surgery who require monitoring for arrhythmias.
7. Patients requiring monitoring for arrhythmias inducing co-morbid conditions such as hyperthyroidism or chronic lung disease.
8. Patients with obstructive sleep apnea to evaluate possible nocturnal arrhythmias.
9. Patients requiring arrhythmia evaluation for etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation.

The MoMe™ System is contraindicated for:

1. Patients with potentially life threatening arrhythmias who require in-patient monitoring.
2. Patients who the attending physician thinks should be hospitalized.
3. Patients with implanted pacemakers, ICDs, neurostimulators and/or body worn medical devices such as insulin pumps.

Intended Population: For Adult Use Only. The MoMe™ Continuous ECG Monitor and Arrhythmia Detector is intended for patients who are 22 years and older.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

Submitter Name:	InfoBionic, Inc.
Submitter Address:	600 Suffolk Street, Lowell, MA 01854
Contact Person:	Carrie Neuberger Regulatory Affairs, InfoBionic
Phone Number:	800-532-4304
Date Prepared:	August 28, 2014
Device Trade Name:	MoMe™ Continuous ECG Monitor and Arrhythmia Detector System
Device Common Name:	Continuous ECG monitor and Arrhythmia Detection System
Product Code and Regulation:	DSI, 21 CFR 820.1025 MLO, 21 CFR 820.2800
Predicate Device #1:	K072588, K093288 CardioNet ECG Monitoring and Arrhythmia Detection System
Predicate Device #2:	K121197, Preventice Body Guardian
Device Description:	The MoMe™ Continuous ECG Monitor and Arrhythmia Detector System (abbreviated to MoMe System in this section) is a remote physiologic monitoring system that detects non-life threatening arrhythmias. The MoMe™ System incorporates a front end device worn by the patient that collects and streams ECG, heart rate and motion (activity) to a dedicated smartphone that continuously transmits the data to remote server. The system then uses proprietary algorithms to continually analyze data and provide reports of detected events. These reports can be accessed anytime, anywhere by a physician using a standard browser or a MoMe iPad App.
Intended Population:	For Adult Use Only. The MoMe™ Continuous ECG Monitor and Arrhythmia Detector is intended for patients who are 22 years and older.

Indications for Use: The MoMe™ System is indicated for use on:

1. Patients who have demonstrated a need for cardiac monitoring and are at low risk of developing primary ventricular fibrillation or sustained ventricular tachycardia.
2. Patients with dizziness or lightheadedness.
3. Patients with palpitations.
4. Patients with syncope of unknown etiology.
5. Patients who require monitoring for non-life threatening arrhythmias, such as atrial fibrillation, other supraventricular arrhythmias, evaluation of various bradyarrhythmias and intermittent bundle branch block.
6. Patients recovering from coronary artery bypass graft (CABG) surgery who require monitoring for arrhythmias.
7. Patients requiring monitoring for arrhythmias inducing co-morbid conditions such as hyperthyroidism or chronic lung disease.
8. Patients with obstructive sleep apnea to evaluate possible nocturnal arrhythmias.
9. Patients requiring arrhythmia evaluation for etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation.

MoMe™ System is contraindicated for:

- Patients with potentially life threatening arrhythmias who require in-patient monitoring.
- Patients who the attending physician thinks should be hospitalized.
- Patients with implanted pacemakers, ICDs, neurostimulators and/or body worn medical devices such as insulin pumps.

Rationale for Substantial Equivalence:

Table 1 Comparison of MoMe™ to Predicate Devices

Characteristics	**InfoBionic MoMe System**	**CardioNet K072588, K093288**	**Preventice K121197**
Product Code/Classification Code	DSI 21CFR 870.1025	DSI 21CFR 870.1025	DSI 21CFR 870.1025
Two ECG leads/channels	Yes	Yes	Yes
Parameters	Arrhythmia detection + ECG, Heart Rate and Activity	Arrhythmia detection	ECG, Heart Rate, Respiration Rate & Activity
Number of electrodes	Four electrodes	Three electrodes	Bandage-like body sensor
Transmission	Bluetooth, cellular	Local wireless, cellular or PSTN	Bluetooth, cellular
Data storage & delivery of report to Users	Remote server	Remote server	Remote server
iPad Display Option	Yes	No	Yes
Multiple monitoring mode options	Holter Event, MCT	Event, MCT	Event, MCT
Physician access to patient physiological and event information	Yes	Yes	Yes

Performance Data: The MoMe System complies with applicable clauses of IEC 60601. The MoMe Arrhythmia detection algorithm has been tested using standard industry practices and in accordance with the FDA Guidance "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm", released October 2003. The Software Verification and Validation reports, MoMe System Verification and Validation report, Algorithm validation report, Transceiver Verification and Validation report, Usability test reports all demonstrate that the MoMe System meets its intended use and design input requirements.

Standards: This submission complies with the following standards:

IEC 60601-1 third edition 2005-12 - General requirements for basic safety and essential performance

IEC 60601-1-2 edition 3 2007-03 General requirements for basic safety and essential performance – Collateral Standard: electromagnetic compatibility – requirements and tests

IEC 60601-1-11 edition1.0 2010-04 - General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-2-47 edition 2.0 2012-02- Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems (Revision of ANSI/AAMI EC 38:2007)

ANSI/AAMI/ISO EC 57:1998/R(2008) - Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms.

ANSI/AAMI EC53:1995/(R)2008 - ECG cables and lead wires (May 2010)

ISO 10993-1:2009 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

ISO 10993-5: 2009 – Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity

ISO 10993-10:2010 – Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Conclusion:

The MoMe System Indications for use are aligned with both the CardioNet and Preventice indications. All three devices are monitoring devices and are classified under the same FDA classification code of 21 CFR 870.1025, DSI. The bench, standards, usability, algorithm and software testing in this submission demonstrate that the MoMe System meets the expected performance requirements for an ECG/Physiological monitor and Arrhythmia detection system, and is therefore equivalent to the predicate devices.