November 15, 2023

Infobionic, Inc.
Carrie Neuberger
Regulatory Consultant To Infobionic Inc.
600 Suffolk Street
Lowell, Massachusetts 01854

Re: K160064
Trade/Device Name: MoMe Kardia Wireless Ambulatory ECG Monitoring and Detection System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: QYX, DSI

Dear Carrie Neuberger:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 11, 2016. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jennifer Kozen, OHT2: Office of Cardiovascular Devices, 301-796-5813, jennifer.kozen@fda.hhs.gov.

Sincerely,

Jennifer W. Shih -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

March 11, 2016

Infobionic, Inc.
Ms. Carrie Neuberger
Regulatory Consultant to Infobionic Inc.
600 Suffolk Street
Lowell, Massachusetts 01854

Re: K160064
Trade/Device Name: MoMe Kardia Wireless Ambulatory ECG Monitoring And Detection System
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
Dated: January 12, 2016
Received: January 13, 2016

Dear Ms. 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160064

Device Name
MoMe® Kardia Wireless Ambulatory ECG Monitoring and Detection System

Indications for Use *(Describe)*
MoMe® Kardia is intended to be used for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.

MoMe® Kardia is contraindicated for:

1. MoMe® Kardia is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias.

Note: MoMe® Kardia does not provide interpretive statements. Interpretation and diagnosis is the responsibility of a physician.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Section 5 510(K) SUMMARY COMPLYING WITH 21 CFR 807.92

Date Prepared: January 12, 2015

Submitter Name: InfoBionic, Inc.

Submitter Address: 600 Suffolk Street, Lowell, MA, 01854

Contact Person: Carrie Neuberger, Regulatory Consultant

Phone Number: 415.640.3377

Device Trade Name: MoMe® Kardia Wireless Ambulatory ECG Monitoring and Detection System

Device Common Name: Continuous ECG monitor and Arrhythmia Detection

Classification Name: Arrhythmia Detector and alarm, 21 CFR 870.1025, DSI

Predicate Device: K100155, Biomedical Systems Corporation's TruVue™ Wireless Ambulatory ECG Monitoring System

Device Description:

MoMe® Kardia is a wireless, remote monitoring system designed to aid physicians in their diagnosis of cardiac arrhythmias in patients with a demonstrated need for cardiac monitoring.

MoMe® Kardia includes the wearable MoMe® Kardia Device that acquires and stores ECG and motion (accelerometer) data and transmits that data via cellular technology to the MoMe® Software System (K152491), a web-based remote server software with proprietary algorithms for analysis, using the MoMe® Device Communications Protocol. MoMe® Software System analyzes the data via the embedded algorithm and when indicated, data identified by the algorithm is flagged for physician review. MoMe® Kardia requires no patient intervention to capture or analyze data however does provide a patient event trigger.

MoMe® Kardia supports three cardiac monitoring modes:

1	Holter
2	Event Monitoring
3	Mobile Cardiac Telemetry (MCT)

MoMe® Kardia:

- Is non-invasive and poses no significant safety issues
- Uses existing electrode and ECG technology
- Is used in an *adjunctive* fashion, where physicians also use patient symptoms and other tests, in the diagnosis or monitoring of patients with cardiac arrhythmias.

MoMe® Kardia is not an emergency service. If the patient is experiencing symptoms that he/she is concerned about, the patient needs to seek immediate medical attention.

Indications for Use:

MoMe® Kardia is indicated for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.

MoMe® Kardia is contraindicated for:

1. MoMe® Kardia is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias.

Note: MoMe® Kardia does not provide interpretive statements. Interpretation and diagnosis is the responsibility of a physician.

Performance Data and Standards Compliance:

The MoMe® Kardia submission was written according to and in conformance with FDA Guidance "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm" released on October 2003. The test reports in the submission demonstrate the MoMe® Kardia meets its intended use and design requirements.

The MoMe® Kardia was tested and conforms to following voluntary FDA recognized standards,

1. IEC 60601-1:2005/R(2012) and A1:2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2:2007/R(2012): Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
3. ANSI/AAMI/IEC 60601-2-47: 2012 Medical electrical equipment- Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

Technological Characteristics:

MoMe® Kardia differs from the predicate device mainly in one area of the device technology and design. The MoMe® Kardia is a single unit body worn device used for acquisition and transmission of ECG data to the monitoring center while the predicate device is a two unit device comprising of a sensor unit to acquire ECG data and a handheld unit which transmits the data to the monitoring center. In predicate device, the sensor unit communicates with cellular modem using Bluetooth technology.

Both the devices, MoMe® Kardia and the predicate device, transmit the recorded ECG data using cellular modem to remote Monitoring centers where the ECG data is analyzed using proprietary software algorithm.

Rationale for Substantial Equivalence:

Parameter	**MoMe® Kardia**	**TruVue™ Wireless Ambulatory ECG Monitoring System**
510(k) Reference Number	Not applicable, this 510(k) submission	K100155
FDA Classification	Class II	Class II
Product Code/ Classification Code/ Common Name	DSI 21 CFR 870.1025 Arrhythmia detector and alarm	DSI 21CFR 870.1025 Arrhythmia detector and alarm
Indications for Use	Indications for use are identical to predicate device. Please refer to Indications for Use in Section 12.2 below.	Refer to Indications for Use in Section 12.2 below
Intended Use	For ECG reporting and arrhythmia detection in patients with non-life threatening arrhythmias	For ECG reporting and arrhythmia detection in patients with non-life threatening arrhythmias
Number of electrodes	3	3
Number of ECG channels	2 channels	2 channels
Ambulatory ECG Performance Standards	IEC60601-2-47	EC 38
ECG Acquisition	Single unit body worn (sensor + cellular module)	Body worn sensor, handheld device with cellular module)
ECG Transmission to Cellular	On board (single unit)	Bluetooth
ECG Transmission to Monitoring Center	Cellular	Cellular

Parameter	**MoMe® Kardia**	**TruVue™ Wireless Ambulatory ECG Monitoring System**
User Event Trigger	Device User Interface	Handheld User Interface
Battery Type	Li Ion rechargeable	Sensor – 1 AAA Monitor – Li Ion rechargeable
Environments where device may be used	Physician practices, clinics, research institutions	Physician practices, clinics, research institutions
Environment where device data storage and reports are generated	Remote (cloud-based) server	Remote (cloud-based) server
Prescription Use	Yes, intended to be used by physicians and health care providers only, not for use by patients	Yes, intended to be used by physicians and health care providers only, not for use by patients
Physician access to patient physiological and event information	Yes	Yes
Arrhythmia detection algorithm	Proprietary/Server side	Proprietary/Server side

Conclusion:

The MoMe® Kardia Indications for Use are the same as the predicate device Indications for Use. The MoMe® Kardia utilizes equivalent operating principles and technology as compared to the predicate device. The descriptive information and performance testing in this submission demonstrate that the MoMe® Kardia meets the expected performance requirements, does not raise new issues of safety or effectiveness, and is therefore substantially equivalent to the predicate device.