



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 17, 2015

InfoBionic, Inc.
Matthew King
Director of Quality Assurance and Regulatory Affairs
600 Suffolk Street
Lowell, Massachusetts 01854

Re: K152491

Trade/Device Name: MoMe Software Platform
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: August 31, 2015
Received: September 1, 2015

Dear Matthew King:

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

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)
K152491

Device Name
MoMe Software Platform

Indications for Use (Describe)

The MoMe® Software Platform is intended to be used for patients 22 years and older that have one or more of the following conditions:

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® Software Platform 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.

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.

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

Date Prepared: August 31, 2015

Submitter Name: InfoBionic, Inc.

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

Contact Person: Matthew King, Director of Quality Assurance and Regulatory Affairs

Phone Number: 978-674-7958

Device Trade Name: MoMe® Software Platform, Model 1300

Device Common Name: Arrhythmia Detector and Alarm

Classification Name: 21 CFR 870.1025, DSI

Predicate Device: MoMe™ ECG Continuous Detection and Arrhythmia Detector, K133753

Device Description:

MoMe® Software Platform is a cloud based arrhythmia analysis and ECG management software system used for Arrhythmia Detection and Monitoring. The system receives ECG and optional activity data from single or multiple lead continuous ECG recorders over a local network or internet connection. This data is evaluated by an arrhythmia analysis algorithm when received, and any detected arrhythmias that the physician has elected to review are presented for physician review. The system provides information on arrhythmias detected, arrhythmia durations, activity levels, heart rate variability and patient reported symptoms. All full disclosure data, events and reports covering the patient monitoring period can be reviewed by a physician through web and mobile applications with secure, role-based authentication. The applications collectively provide for patient data entry, event review, creation of reports, and association of devices with patient records.

The MoMe® Software Platform supports three cardiac monitoring modes:

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

MoMe® Software Platform processes recorded cardiac monitoring data from ECG Devices that adhere to the data formats and communications protocol described in the Device Communications Protocol (10094), and may be reviewed at anytime, anywhere by a physician

using a standard browser with web access. Data may also be exported for additional review and reporting if desired.

MoMe® Software Platform is intended to provide information that assists the physician, along with patient symptoms and other tests, in the diagnosis or monitoring of patients with cardiac arrhythmias.

MoMe® Software Platform 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:

The MoMe® Software Platform is intended to be used for patients 22 years and older that have one or more of the following conditions:

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® Software Platform 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.

Performance Data and Standards Compliance:

The MoMe® Software Platform complies with the following standards as documented in the test reports provided in this 510(k) submission. The MoMe® Software Platform Arrhythmia detection algorithm has been testing using standard industry practices and in accordance with the FDA Guidance "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm" released October 2003. Software verification and validation reports demonstrate the MoMe® Software Platform meets its intended use and design requirements.



ANSI/AAMI/IEC 606012-47:2012 - Medical electrical equipment— Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.

ANSI/AAMI EC57:2012- Testing and reporting performance results of cardiac arrhythmia and ST segment measurement algorithms.

Technological Characteristics:

The MoMe® Software Platform, like the predicate device (MoMe™ ECG Continuous Detection and Arrhythmia Detector, K133753), uses a cloud based arrhythmia analysis and ECG management system for arrhythmia detection and monitoring. The predicate device includes a dedicated MoMe ambulatory ECG recorder to collect ECG data (called MoMe transceiver) and a Smartphone to transmit the ECG data to the arrhythmia detection and monitoring software in the cloud. The MoMe® Software Platform is a software only product, so there are no materials of construction or physical properties to describe. It is designed to be compatible with any ambulatory electrocardiograph ECG recorder that adheres to the data formats and communications protocol described in the Device Communications Protocol included in this 510k.

As with the predicate device, the Software Level of Concern for the MoMe® Software Platform has been evaluated in accordance with the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* dated May 11, 2005 and with InfoBionic’s Risk/Hazard Analysis.

Rationale for Substantial Equivalence:

Characteristics	MoMe® Software Platform	MoMe™ ECG Continuous Detection and Arrhythmia Detector (K133753)
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	Refer to Indications For Use section; same as predicate	Refer to Indications For Use are section
Parameters	Arrhythmia detection and ECG reporting, Heart Rate, Activity	Arrhythmia detection and ECG reporting, Heart Rate, Activity
Data source	ECG Devices that adhere to the data formats and communications protocol described in the Device Communications Protocol (10094)	Dedicated MoMe ECG front end device (complies with MoMe Device Communications Protocol).



Characteristics	MoMe® Software Platform	MoMe™ ECG Continuous Detection and Arrhythmia Detector (K133753)
Data storage & delivery of report to Users	Remote server	Remote server
Display Options	Computer or Tablet	Computer or Tablet
Multiple monitoring mode options	Holter, Event, MCT	Holter Event, MCT
Physician access to patient physiological and event information	Yes	Yes
Number of ECG Channels	1 – 2 channels	2 channels

Conclusion: The MoMe® Software Platform Indications for Use are the same as the MoMe™ ECG Continuous Detection and Arrhythmia Detector Indications for Use. Both devices are arrhythmia analysis and ECG management systems used for Arrhythmia Detection and Monitoring and are classified under the same FDA classification code of 21 CFR 870.1025, Product Code: DSI. The standards, usability, algorithm and software testing in this submission demonstrate that the MoMe® Software Platform meets the expected performance requirements, does not raise new issues of safety or effectiveness to the predicate arrhythmia detector and alarm device that has been cleared for commercial distribution, and is therefore substantially equivalent to the predicate device.