October 6, 2023

InfoBionic, Inc.
% Rita King, CEO, MethodSense, Inc.
1 Copley Pkwy, Suite 410
Morrisville, North Carolina 27560

Re: K230265
Trade/Device Name: MoMe® ARC 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 30, 2023
Received: January 31, 2023

Dear Rita 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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Shruti N. Mistry -S

Jennifer Shih 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230265

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

Indications for Use *(Describe)*

MoMe® ARC 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® ARC is contraindicated for:

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

Note: MoMe® ARC 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.

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510(k) Summary

InfoBionic K230265

This 510(k) Summary is in conformance with 21CFR 807.92

Submitter: InfoBionic, Inc.
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Date Prepared: September 1, 2023

Device Name and Classification

Trade Name: MoMe® ARC Wireless Ambulatory ECG Monitoring and Detection System
Common Name: Continuous ECG Monitor and Arrhythmia Detection
Classification: Class II
Regulation Number: 21 CFR Part 870.1025
Classification Panel: Cardiovascular
Product Code: DSI

Predicate Device:

Primary Predicate	
Trade Name	MoMe® Kardia Wireless Ambulatory ECG Monitoring and Detection System
Common Name	Continuous ECG monitor and Arrhythmia Detection
510(k) Submitter / Holder	InfoBionic, Inc.
510(k) Number	K160064
Regulation Number	21 CFR Part 870.1025
Classification Panel	Cardiovascular
Product Code	DSI

The predicate device has not been subject to a design-related recall.

Device Description and Intended Use
MoMe® ARC 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.

The MoMe® ARC device primarily consists of a Sensor, Gateway, and Charging dock with accessories. The body worn Sensor acquires, stores, and forwards ECG data to the Gateway using a 2.4GHz BLE wireless link; and the Gateway stores and forwards ECG signal data to the MoMe® Software Platform (K152491) over a 4G LTE cellular link.

The Sensor and Gateway incorporate non-removable, rechargeable batteries, with the Gateway battery being wirelessly charged by the charging dock and the sensor battery being wirelessly charged by Gateway. The user interface is composed of a mechanical button, display with touch screen, vibrator, and a speaker on the Gateway and a vibrator and LED on the Sensor.

The MoMe® ARC communicates with the MoMe® Software System (K152491), a web-based remote server software with proprietary algorithms for analysis, using the MoMe® Device Communications Protocol. The MoMe® Software System analyzes the data via the embedded algorithm and when indicated, data identified by the algorithm is flagged for physician review.

Once activated and operating normally the system requires no patient intervention to capture or analyze data. However, the MoMe® ARC has a patient triggered Event feature that allows for selection and recording of their symptoms if desired.

The device is intended for use under prescription only for monitoring patients with suspected cardiac arrhythmias.

MoMe® ARC:

- 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® ARC 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.

The intended use of the MoMe® ARC is for ECG reporting and arrhythmia detection in patients with non-life threatening arrhythmias.

Indications for Use
MoMe® ARC 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® ARC is contraindicated for:

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

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

Substantial Equivalence
The table below provides a detailed comparison of MoMe® ARC to the predicate device.

Characteristic	**Subject Device MoMe® ARC K3**	**Predicate Device MoMe® Kardia (K160064)**	**Comparison**
FDA Classification	Class II	Class II	Identical
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	Identical
Indications for Use	Please refer to Indications for Use in the "Substantial Equivalence" section above.	Please refer to Indications for Use in the "Substantial Equivalence" section above.	Equivalent. Name change from MoMe® Kardia to MoMe® ARC.
Product Code / Classification Code / Common Name	DSI 21 CFR 870.1025 Arrhythmia detector and alarm	DSI 21 CFR 870.1025 Arrhythmia detector and alarm	Identical
Number of electrodes	3	3	Identical
Number of ECG Channels	2 Channels	2 Channels	Identical
Ambulatory ECG Performance Standards	IEC 60601-2-47	IEC 60601-2-47	Identical
ECG Acquisition	Body worn sensor, handheld device with cellular module	Single unit body worn (sensor and cellular model)	Equivalent. Refer to Note 1 below.
ECG Transmission to Cellular	Bluetooth	On board (single unit)	Different. Refer to Note 1 below.
ECG Transmission to Monitoring Center	Cellular	Cellular	Identical

Characteristic	Subject Device MoMe® ARC K3	Predicate Device MoMe® Kardia (K160064)	Comparison
User Event Trigger	Device User Interface	Device User Interface	Identical
Battery Type	Li Ion rechargeable	Li Ion rechargeable	Identical
Environments where device may be used	Physician practices, clinics, research institutions	Physician practices, clinics, research institutions	Identical
Environment where device data storage and reports are generated	Remote (cloud-based) server	Remote (cloud-based) server	Identical
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.	Identical
Physician access to patient physiological and event information	Yes	Yes	Identical
Arrhythmia Detection Algorithm	Proprietary/Server Side	Proprietary/Server Side	Identical

Note 1. The predicate device, MoMe® Kardia (K160064) transmitted the ECG data between the Sensor and Gateway via a hard-wired connection. The subject device, MoMe® ARC, transmits the ECG data between the Sensor and Gateway via a Bluetooth connection. This change in ECG transmission additionally allows for just the sensor component to be worn during acquisition and the gateway to be considered a hand-held device. This change of data transfer method has been validated through testing to demonstrate that this difference does not affect the safety and effectiveness of the device.

Performance Testing – Nonclinical

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

The MoMe® ARC was tested and conforms to the following voluntary FDA recognized standards:

1. ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

   Note: Has been tested and complies with the requirements of Clause 8.5.5.2 - Energy reduction test.

2. IEC 60601-1-2: Edition 4.1 2020-09 Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
3. ANSI/AAMI/IEC 60601-2-47: 2012/(R)2016 Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
4. IEC /TR 60601-4-2 Edition 1.0 2016-05 Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
5. FIRST CVSS v3.0 Common Vulnerability Scoring System version 3.0
6. IEEE ANSI USEMCSC C63.27-2021 American National Standard for Evaluation of Wireless Coexistence
7. ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
8. ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
9. ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization ISO 10993-12 Fifth edition 2021-01 Biological evaluation of medical devices - Part 12: Sample preparation and reference material
10. 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

Performance Testing – Clinical

No clinical tests were required to demonstrate substantial equivalence.

Conclusion

Based on the nonclinical performance testing, comparison, and analysis in this submission for the MoMe® ARC device, MoMe® ARC is as safe and effective (i.e. substantially equivalent) as the legally marketed predicate device, K160064.