July 29, 2025

InfoBionic, Inc.
% Rita King
CEO
MethodSense, Inc.
1 Copley Pkwy
Suite 130
Morrisville, North Carolina 27560

Re: K250356
Trade/Device Name: MoMe ARC® Wireless Ambulatory ECG Monitoring and Detection System (32000)
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: July 1, 2025
Received: July 1, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

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

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.

Submission Number *(if known)*

K250356

Device Name

MoMe ARC® Wireless Ambulatory ECG Monitoring and Detection System (32000)

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.
2. MoMe ARC® is not intended for use on infants weighing less than 10kg (22lbs.). Clinical judgement is necessary to determine if the MoMe ARC® is appropriate for specific pediatric patients.
3. The patch configuration of the MoMe ARC® is contraindicated for monitoring QT intervals for patients taking Class III antiarrhythmic drugs.

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.

Summary of 510(k)

InfoBionic K250356

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

Submitter: InfoBionic, Inc.
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Date Prepared: June 30, 2025

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:

	Predicate Device	Reference Device
Trade Name	MoMe® ARC Wireless Ambulatory ECG Monitoring and Detection System	Braemar Telemetry Patch System Model BTPS-1000
Common Name	Continuous ECG monitor and Arrhythmia Detection	Arrhythmia detector and alarm
510(k) Submitter / Holder	InfoBionic, Inc.	Braemar Manufacturing, LLC
510(k) Number	K230265	K153473
Regulation Number	21 CFR Part 870.1025	21 CFR Part 870.1025
Classification Panel	Cardiovascular	Cardiovascular
Product Code	DSI	DSI

The predicate and reference devices have not been subject to design-related recalls.

Device Description
The MoMe ARC® device consists of a Sensor Pod, Leads, Gateway, and Charging Cradle with accessories. The body worn Sensor Pod acquires, stores and forwards electrocardiogram (ECG) data from Leads in a Wired Lead-Set or in a Patch to the Gateway using a 2.4GHz BLE wireless link. The Gateway consists of an OTS mobile device running the MoMe ARC® Gateway Mobile App. The Gateway is a Medical Device Data System (MDDS) which stores and forwards the ECG signal data to the MoMe Software Platform (K152491) via a wireless cellular link.

The MoMe ARC® communicates with the MoMe Software Platform (K152491), a web-based remote server software with proprietary algorithms for analysis, using the MoMe Device Communications Protocol. The MoMe Software System (K152491) 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 an optional patient triggered event feature that allows for manual selection and recording of patient symptoms, if and when desired.

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

The MoMe ARC®:
- Is non-invasive and poses no significant safety issues;
- Uses existing electrode and patch ECG technology; and
- Is used in an adjunctive fashion, where physicians also use patient symptoms and other tests, in the diagnosis or monitoring of patients with suspected 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.

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.

2. MoMe ARC® is not intended for use on infants weighing less than 10kg (22lbs.). Clinical judgement is necessary to determine if the MoMe ARC® is appropriate for specific pediatric patients.

3. The patch configuration of the MoMe ARC® is contraindicated for monitoring QT intervals for patients taking Class III antiarrhythmic drugs.

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 and reference devices.

Characteristic	Subject Device MoMe ARC®	Predicate Device MoMe ARC® (K230265)	Reference Device Braemar Telemetry Patch System, Model BTPS-1000 (K153473)	Comparison
Intended Use				
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	For ECG reporting and arrhythmia detection in patients with non-life threatening arrhythmias	Identical
Indications for Use				
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	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 carious 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	The device is designated as Rx only. Its indications for use are as follows: 1. Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.	Equivalent to the predicate.

	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. 2. MoMe ARC® is not intended for use on infants weighing less than 10kg (22lbs.). Clinical judgement is necessary to determine if the MoMe ARC® is appropriate for specific pediatric patients. 3. The patch configuration of the MoMe ARC® is contraindicated for monitoring QT intervals for patients taking Class III anti arrhythmic drugs. Note: MoMe ARC® does not provide interpretive statements. Interpretation and diagnosis is the responsibility of a physician.	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.	2. Patients with symptoms that may be due to cardiac arrhythmias. They may include by 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; c) dyspnea (shortness of breath). 3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms. 4. Patients who require outpatient monitoring of antiarrhythmic therapy: a) Monitoring of therapeutic and potential proarrhythmic effects of membrane active drugs, b) Monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation) 5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring 6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias 7. Patients requiring arrhythmia evaluation of etiology of stroke or	

Characteristic	Subject Device MoMe ARC®	Predicate Device MoMe ARC® (K230265)	Reference Device Braemar Telemetry Patch System, Model BTPS-1000 (K153473)	Comparison
			transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter. 8. Patients requiring measurement, analysis and reporting of QT interval, excluding patients with a documented history of sustained atrial fibrillation or atrial flutter 9. Patients who require monitoring for potential arrhythmias based on risk factors (e.g. atrial fibrillation). 10. Patients requiring measurement of ST segment changes. The device is not intended to sound any alarms for ST segment changes. Contraindications: 1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring. 2. Patients who the attending physician recommends should be hospitalized for ECG monitoring. 3. This device should not be used for monitoring of QT interval during the initiation of antiarrhythmic therapy, where in-hospital monitoring is required by the labeling of that drug.	

Characteristic	Subject Device MoMe ARC®	Predicate Device MoMe ARC® (K230265)	Reference Device Braemar Telemetry Patch System, Model BTPS-1000 (K153473)	Comparison
			4. The device does not replace the QT interval measurement by a trained observer using diagnostic 12 lead ECG in a clinical environment. This device is not intended to sound any alarms for QT interval changes. 5. The device does not annotate QT interval for QRS durations > 160ms or for T wave amplitudes less than or equal to 5% of the peak amplitude.	
Product Code				
Product Code	DSI (21 CFR 870.1025)	DSI (21 CFR 870.1025)	DSI (21 CFR 870.1025)	Identical
Device Use				
Prescription Use	Prescription only	Prescription only	Prescription only	Identical
Intended Population	Patients > 10kg (22lbs)	Patients > 10kg (22lbs)	Patients > 10kg (22lbs)	Identical
Environment of Use	Physician practices, clinic, research institutions, home environments	Physician practices, clinic, research institutions, home environments	Physician practices, clinic, home environments	Identical
Environment Where Device Data is Stored and Reports are Generated	Remote (cloud-based) server	Remote (cloud-based) server	Remote server	Identical
Technological Characteristics				

Characteristic	Subject Device MoMe ARC®	Predicate Device MoMe ARC® (K230265)	Reference Device Braemar Telemetry Patch System, Model BTPS-1000 (K153473)	Comparison
Patient Contacting Material	• Polycarbonate • 3M 1774W Thin White Polyolefin Foam Tape • 3M 4076 SC White Spunlace Nonwoven Extended Wear Tape • Axelgard AG600 Hydrogel • TPV thermoplastic vulcanizate (Celanese, Santoprene TPV 8281-90MED) • TPE thermoplastic elastomer (GLS Corp, Versaflex OM 3060-1)	• Polycarbonate • Soda-Lime Glass • TPU – thermoplastic polyurethane (DIOSHY TPU-T995M) • TPV thermoplastic vulcanizate (Celanese, Santoprene TPV 8281-90MED) • TPE thermoplastic elastomer (GLS Corp, Versaflex OM 3060-1)	• 3M Siliconized Backing Paper (3M 9834) • 3M Non-Woven PET Film (3M 2476P) • Hydro Gel Pad AG602 • PET: Kemafoil HSPL 80W	Different – This difference does not change the intended use of the device. No additional questions of safety and effectiveness are introduced compared to the predicate.
Size	59 mm x 39 mm x 11 mm	108 mm x 67 mm x 17 mm	50.8 mm x 40.64 mm x 9.144 mm	Different – The dimensions of the predicate device included the Gateway Device. The difference does not change the intended use of the device. No additional question of safety and effectiveness are introduced compared to the predicate.
Energy Source	Rechargeable Li-ion	Rechargeable Li-ion	Rechargeable Li-ion	Identical
Device Components	Body-worn Sensor, Handheld Gateway, Patch	Body-worn Sensor, Handheld Gateway	Body-worn Sensor, Monitor, Patch	Equivalent to reference device.
Software / Firmware	Yes	Yes	Yes	Identical
Sterilization Method	Non-sterile	Non-sterile	Non-sterile	Identical
Use Type	Multi-patient use (Sensor, Gateway, Leads) and disposable patch	Multi-patient use (Sensor, Gateway, Leads) and disposable electrodes	Multi-patient use (Sensor, Monitor) and disposable patch	Identical

Characteristic	Subject Device MoMe ARC®	Predicate Device MoMe ARC® (K230265)	Reference Device Braemar Telemetry Patch System, Model BTPS-1000 (K153473)	Comparison
Number of electrodes	1 Patch, or 3 disposable electrodes	3 Disposable Electrodes	1 Patch	Equivalent to reference device.
Number of ECG channels	1 or 2 Channels	2 Channels	1, 2, or 3 Channels	Equivalent to reference device.
Ambulatory ECG Performance Standards	IEC 60601-2-47	IEC 60601-2-47	IEC 60601-2-47	Identical
ECG Acquisition	Body worn sensor, handheld device with cellular module	Body worn sensor, handheld device with cellular module	Body worn sensor; handheld device with cellular module	Identical
ECG Transmission to Cellular	Bluetooth	Bluetooth	Bluetooth	Identical
ECG Transmission to Monitoring Center	4G Cellular	4G Cellular	Cellular	Identical
User Event Trigger	Handheld device user interface	Handheld device user interface	Handheld device user interface	Identical
Physician Access to Patient Physiological and Event Information	Yes	Yes	Yes	Identical
Arrhythmia Detection Algorithm	Proprietary / Server Side	Proprietary / Server Side	Proprietary	Identical

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" (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. ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - 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 v4.0 Common Vulnerability Scoring System version 4.0
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 10993-2:2022 Biological evaluation of medical devices – Part 2: Animal welfare requirements
9. ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
10. ISO 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for skin sensitization
11. ISO 10993-12:2021 Biological evaluation of medical devices – Part 12: Sample preparation and reference material
12. ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Tests for irritation
13. IEC 60601-1-11:2015 + A1:2020 Medical electrical equipment – Part 1-11: 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
14. ANSI/AAMI EC12:2000(R) 2020 - Disposable ECG electrodes
15. ASTM F1980 – 21: Accelerated Aging of Sterile Barrier Systems and Medical Devices
16. ANSI AAMI EC57:2012 Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms

Performance Testing – Clinical

Clinical testing was performed to validate the performance of the Software Platform (K152491) with the MoMe ARC® 1-lead patch system (Subject Device).

Clinical data were prospectively collected from 87 adult subjects at a single U.S. clinic. Each subject served as their own control and was assigned to one of two cohorts:

- Inpatient (n = 75): Patients admitted to the hospital and undergoing continuous cardiac telemetry monitoring
- Outpatient (n = 12): Patients undergoing prescribed ambulatory monitoring for cardiac arrhythmia detection and analysis.

Demographics

- Sex: 64 male, 23 female
- Age: 21-87 years (mean 65.2 years)

Study Objectives

- Primary: Collect data from a single-lead ECG patch device for evaluation using InfoBionic ECG automated algorithms (FDA 510(k) = K152491).
- Secondary: Collection of data on a single-lead ECG patch device in patients admitted to a hospital that are currently being monitored with continuous cardiac telemetry.

No adverse events occurred during or after enrollment. Data from all 87 subjects were adjudicated by Certified Cardiac Technicians (CCTs) using Holter software, with beat locations, morphologies, and arrhythmia annotations serving as the reference standard. The Software Platform's sensitivity and positive predictivity were calculated using ANSI/AMI/IEC EC57:2012 methods.

Key Results

- Sensitivity: Met predefined acceptance criteria for arrhythmia detection.
- Positive Predictivity (+P): Met predefined acceptance criteria versus CCT reference.
- Heart-Rate Accuracy: Mean absolute error of ± 0.247 bpm compared to reference.

These results provide objective evidence that the MoMe Software platform algorithm accurately detects and triggers abnormal rhythms noted on MoMe ARC® 1-Lead Patch ECG tracings in both inpatient and outpatient environments, supporting the subject device's safety and effectiveness for its intended use as compared to the predicate.

Conclusion

In conclusion, the intended use of the MoMe ARC® is identical to the intended use of the predicate device (K230265). The technological characteristics of the MoMe ARC® are equivalent to those of the predicate (K230265) and reference (K153473) devices. Testing has demonstrated that the MoMe ARC® is substantially equivalent to, and as safe and effective as, the predicate (K230265) and reference (K153473) devices.