October 31, 2024

SmartCardia SA
% Robert Steurer
Consultant
Steurer Consulting Group LLC
800 Blue Quail Rd
Keller, Texas 76248

Re: K240653
Trade/Device Name: SmartCardia 7L 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: QYX, DSI, DRG
Dated: October 1, 2024
Received: October 2, 2024

Dear Robert Steurer:

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.

510(k) Number *(if known)*
K240653

Device Name
SmartCardia 7L Platform

Indications for Use *(Describe)*
The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for continuous external electrocardiogram (ECG) information to support Holter Monitoring, Extended Holter Monitoring, and Outpatient Cardiac Telemetry (OCT) commonly called Mobile Cardiac Telemetry (MCT) monitoring.

The SmartCardia 7L Platform is intended 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 Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures.
The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:
1. The SmartCardia 7L Platform is contraindicated for use for detection or notification of hemodynamically unstable or life-threatening arrhythmias or cardiac events requiring urgent medical response. It is not intended for monitoring patients during cardiac rehabilitation outside of healthcare facilities.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared:	October 28, 2024
Submitter:	SmartCardia SA EPFL Innovation Park Building C 1015, Lausanne, Switzerland Srinivasan Murali SmartCardia SA Phone: +41 7887 50864 Fax: N/A Email: srinivasan.murali@smartcardia.com
Application Correspondent:	Robert Steurer Principal Consultant Steurer Consulting Group 800 Blue Quail Rd. Keller, TX 76248 steurerbob@gmail.com +1 (425) 358-1072
Manufacturing Site:	SmartCardia SA EPFL Innovation Park Building C 1015, Lausanne, Switzerland
Common Name:	SmartCardia 7L Platform
Classification Name:	Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Device Class:	Class II
Primary Classification Regulation:	21 CFR 870.1025
Primary Product Code:	QYX
Secondary Codes:	DSI,DRG
Primary Predicate Device:	InfoBionics MoMe Kardia, K160004
Reference Predicate Device:	SmartCardia 7L Platform, K231276

Device Description:

The SmartCardia 7L Platform MCT is a body worn monitoring product that is designed with a disposable adhesive 7L Patch and reusable 7L Sensor. It is designed to be worn by the patient for up to 14 days. If longer monitoring is necessary, the 7L Patch is removed from the body, the 7L Sensor is removed from the worn 7L Patch which is discarded. The 7L Sensor is inserted into a new 7L Patch and the new assembly is placed on the patient for monitoring to continue.

The 7L Sensor/7L Patch assembly communicates to the SmartCardia Phone via Bluetooth technology and shows the patient's heart rate and ECG on its display and allows the patient to input symptoms (Mark Event) which are shown in the patient record. The SmartCardia Phone has a medical grade mains powered charger and uses its cellular technology to act as a gateway to the SmartCardia Cloud Service provided by Amazon Web Services. The SmartCardia Phone is pre-configured by SmartCardia and placed in a kiosk mode. Data stored in the SmartCardia cloud can be viewed in the SmartCardia Web Browser application by a clinician or healthcare provider. The SmartCardia 7L Platform incorporates three modes of monitoring:

1. Holter Monitoring (up to 48 hours) and Extended Holter Monitoring (>48 hours and up to 14 days),
2. Event Monitoring (up to 48 hours, and >48 hours up to 14 days)
3. Cardiac Outpatient Telemetry (OCT) commonly called Mobile Cardiac Telemetry (MCT) (>48 hours up to 30 days when changing the 7L Patch)

During any of the selected modes, a clinician or healthcare provider can use the SmartCardia Web Browser to view the continuously streaming patient's ECG.
The SmartCardia 7L Platform provides alarm notifications for heart rate and atrial fibrillation. As stated in the Intended Use statement, the system is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required. There are no alarm signals presented to the clinician for conditions other than heart rate and atrial fibrillation.
The SmartCardia 7L Platform performs retrospective analysis and identifies events which it shows the clinician when they are reviewing historical data. The clinician must then review these events and determine if they are indeed valid and should be included in a physician's report. These events are things like "Ventricular Bigeminy', 'Supraventricular Couplet', etc. A full list is included in the Clinician Instructions for Use.

Intended Use / Indications for Use:

The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for continuous external electrocardiogram (ECG) information to support Holter Monitoring, Extended Holter Monitoring, and Outpatient Cardiac Telemetry (OCT) commonly called Mobile Cardiac Telemetry (MCT) monitoring.
The SmartCardia 7L Platform is intended 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. Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:

1. The SmartCardia 7L Platform is contraindicated for use for detection or notification of hemodynamically unstable or life-threatening arrhythmias or cardiac events requiring urgent medical response. It is not intended for monitoring patients during cardiac rehabilitation outside of healthcare facilities.

2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

Summary of Substantial Equivalence:

Substantial Equivalence – Predicate Device: InfoBionics MoMe Kardia, K160064
Intended Use:

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.

Substantial Equivalence – Intended Use Comparison Statement:
The indications for use of the InfoBionics MoMe Kardia predicate device and the SmartCardia 7L Platform MCT device are substantially equivalent. The SmartCardia 7L Platform MCT adds Outpatient Cardiac Telemetry, commonly called Mobile Cardiac Telemetry as a mode of operation in its indications for use. The user population and environment of operation are the same. The product code is changed to the newly released QYX. The regulation number and special controls are the same as the predicate product code DSI, 870.1025.

The subject device SmartCardia 7L Platform MCT is an update to the Reference Predicate Device SmartCardia 7L Web Browser software. The data acquisition uses the same technology as the predicate device.

1) The same SmartCardia 7L Sensor and 7L Patch communicate wirelessly to the same SmartCardia Phone that transmits the data to the same SmartCardia 7L cloud based server for storage and further analysis.

2) The SmartCardia 7L Platform MCT has three modes of operation for Holter, Extended Holter and Event monitoring. All of these modes of operation provide continuous streaming of the ECG for viewing by a clinician or qualified cardiac technician in the same manner as the Predicate Device.The subject SmartCardia 7L Platform MCT updates the platform to include Outpatient Cardiac Telemetry (OCT) which is commonly called Mobile Cardiac Telemetry (MCT) as a mode of operation. The use of the SmartCardia 7L Platform MCT for Mobile Cardiac Telemetry is manged by SmartCardia through its supplier control requirements, personnel access limitations, monitoring settings, and timely notifications by an independent diagnostic testing facility (IDTF) personnel.

Non-Clinical Bench Performance Testing Summary:

The SmartCardia 7L Platform was tested for compliance with FDA Guidance “Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm” released October 28, 2003.

Additional non- clinical bench performance testing was done per the following:

- Basic Safety and Essential Performance per IEC 60601-1
- Electromagnetic Compatibility per IEC 60601-2
- Wireless Coexistence testing per FDA Guidance document “Radio Frequency Wireless Technology in Medical Devices, August 14, 2013”, and exposure to RFID devices per AIM 7351731.
- Wireless Coexisting testing per ANSI C63.27: 2017
- ECG Monitoring for Ambulatory ECG devices per IEC 60601-2-47
- Life Cycle testing per IEC 60601-11 Home Healthcare
- ECG electrode testing per ANSI/AAMI EC12
- Cleaning and disinfection methods as defined by SmartCardia SA
- ECG Waveform Quality and Wearability
- Effects of Sensor Positioning on ECG Performance
- DVR-66 SCDB ECG Test Results (algorithm testing and reporting) per EC57

Objective(s) of the Test(s):
To test the claimed ranges of measurement provided in the specification and labeling that support the intended use and three monitoring modes of operation: Holter and Extended Holter (Ambulatory electrocardiographic monitoring, Event Monitoring.

Test Methods

Bench testing was performed on an end-to-end system using electronic patient simulators and/or electronic test equipment (signal generators, etc.). This was performed per the applicable standards using production equivalent units.

Pass/Fail Criteria

Pass criteria is compliance with the claimed range and precision provided in the labeling for the SmartCardia 7L Platform. Deviations from the recognized standard criteria are identified in the applicable test report.

Results Summary

Testing showed that the SmartCardia 7L Platform met the pass/fail criteria established by the appropriate standards. The SmartCardia 7L Platform is contraindicated for use during defibrillation and is visibly labeled to indicate removal during defibrillation. Defibrillator protection testing was performed to ensure there was not excessive energy shunted away from the patient during defibrillation.

To verify the reproduction of the ECG and ensure that there are not significant morphological changes that could impact the measurements and/or classifications, SmartCardia SA performed verification testing using a standard 12 lead ECG machine and comparing the morphology and ECG characteristics. The result of this testing is included in the document, DVR-67-01 ECG Waveform Quality and Wearability Report is included in this section.

The ECG detection algorithm was tested per ANSI/AAMI EC57 standard for testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms. The SmartCardia 7L Platform does not claim ST analysis or measurements. Therefore, the sections of the EC57 standard relating to ST measurement is not applicable. Because of the nature of the SmartCardia 7L Platform as a body worn sensor and patch device with the electrodes in close proximity to each other, and not utilizing ECG lead wires such as a traditional ECG device, SmartCardia developed a protocol and database for evaluating the analysis algorithm. The results show that the SmartCardia 7L Platform algorithm detection and reported results for the stated output arrhythmia were satisfactory and met industry norms.

Discussion/Conclusion: Based on a review of the test results and a comparison to the predicate devices characteristics and known specifications, the results show that the SmartCardia 7L Platform is substantially equivalent to the predicate and reference devices.