July 9, 2026

Lifesignals, Inc.
Saravanan Balasubramanian
Vice President - Global, Medical Technology & Regulatory Operations
426 S Hillview Dr.
Milpitas, California 95035

Re: K261569
Trade/Device Name: UbiqVue™ 2AYe Cardiac System (UX2253)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, QYX, MWJ, DXH
Dated: May 11, 2026
Received: May 12, 2026

Dear Saravanan Balasubramanian:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261569

Please provide the device trade name(s).

UbiqVue™ 2AYe Cardiac System (UX2253)

Please provide your Indications for Use below.

The UbiqVue™ 2AYe Cardiac System is intended to capture, record for analysis and report both symptomatic and asymptomatic cardiac events, along with continuous electrocardiogram (ECG) information, for long-term monitoring. Following patient monitoring using the UbiqVue™ 2AYe Wearable Biosensor, a comprehensive final report is generated from the entire ECG recording. Optionally, intended users may choose to generate an interim report from periodically or intermittently transferred ECG recording wirelessly from the UbiqVue™ 2AYe Wearable Biosensor. Final & interim reporting is based on the beat-to-beat information extracted from the ECG recording.

The UbiqVue™ 2AYe Cardiac System is intended for non-critical, adult population, who are 18 years of age or older, at home and in healthcare settings, who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reports are provided for review by the intended user to render a diagnosis based on their clinical judgment and experience.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary for
UbiqVue™ 2AYe Cardiac System

1 Background : LifeSignals, Inc.

Address : 426 S Hillview Drive
Milpitas, CA 95035.
USA
Contact : Saravanan Balasubramanian
Vice President – Global, Medical Technology & Regulatory Operations
Email: saravanan@lifesignals.com
Tel: 510.770.6412 Ext. 4

2 Date prepared : May 11, 2026

3 Device

Trade Name : UbiqVue™
Model Name : 2AYe Cardiac System
Common Name : Transmitters and Receivers, Physiological Signal, Radio Frequency

4 Classification Product code

	Regulation Classification	Product Code	Description
Cardiovascular	21 CFR 870.2910 Class II	DRG	Transmitters and Receivers, Physiological Signal, Radio frequency

5 Subsequent Product code

	Regulation Classification	Product Code	Description
Cardiovascular	21 CFR 870.2920 Class II	DXH	Transmitter and Receivers, Electrocardiograph, Telephone
Cardiovascular	21 CFR 870.2800 Class II	MWJ	Medical magnetic tape recorder
Cardiovascular	21 CFR 870.1025 Class II	QYX	Outpatient cardiac telemetry

6 Predicate & Reference Devices

Primary Predicate Device:

510(k) Number : K200690
Model : LifeSignals ECG Remote Monitoring Patch Platform
Manufacturer : LifeSignals, Inc. USA

Secondary Predicate Device:
510(k) Number : K163512
Model : Zio AT/QX ECG Monitoring System
Manufacturer : iRhythm Technologies, Inc. USA

Reference Device (for Biosensor Technology & Software Architecture):
510(k) Number : K242018
Model : UbiqVue™ 2A Multiparameter System
Manufacturer : LifeSignals, Inc. USA

7 Device description

UbiqVue™ 2AYe Cardiac System consist of below components:

- UbiqVue™ 2AYe Wearable Biosensor
- UbiqVue™ Holter Mobile App
- UbiqVue™ Relay Bridge
- UbiqVue™ Holter Central Server
- UbiqVue™ Holter Web Server
- UbiqVue™ Holter Web Portal

UbiqVue™ 2AYe Wearable Biosensor acquires ECG signals from the body, pre-processes as two channels of ECG data which is wirelessly transmitted to UbiqVue Central Server via any UbiqVue™ Relay devices (UbiqVue™ Holter Mobile App or UbiqVue™ Relay Bridge). If the receiver device is not available or not communicating, the data shall be buffered locally in Biosensor till the wireless connection is re-established and resume communication. The UbiqVue™ 2AYe Wearable Biosensor is completely disposable and has a battery life, storage memory & intended for wear-life of 8 days. Patients can also record any symptom events by pressing the ON/Event button on the Biosensor.

UbiqVue™ 2AYe Wearable Biosensor is technologically similar & subset of *UbiqVue™ 2A Wearable Biosensor* used in *UbiqVue™ 2A Multiparameter system* (Reference device - K242018).

UbiqVue™ Holter Mobile App is intended to be used by patients to retrieve the data from Biosensor and transfer to the UbiqVue™ Holter Central Server. Registered patients can download the App in smart phone (iOS or Android) and establish connection with the Biosensor. The App will automatically communicate (sync) with UbiqVue 2AYe wearable Biosensor through BLE (5.1) for every 10 minutes (approximately) throughout the Holter procedure, retrieving the acquired ECG data from Biosensor and transferring to UbiqVue Holter Central Server. For any symptom events (button presses on the Biosensor), patients can enter description of symptoms & associated activity electronically through UbiqVue™ Holter Mobile App.

UbiqVue™ Relay Bridge Software which is already regulatory cleared (Reference device K242018) is intended to be used by Clinical personnel as an alternate method of ECG data retrieval from the Biosensor after the Holter procedure is completed. This software shall be installed on an Open WRT based Access Point (Router) and shall wirelessly connect to one or more Biosensor at a time via Wi-Fi, retrieving the acquired ECG data and transferring to UbiqVue™ Holter Central Server.

UbiqVue™ Holter Central Server Software installed in a cloud server, receives, stores & provide access to ECG data retrieved from Biosensors after the Holter Procedure (or during the Holter procedure). The stored ECG data is identified with the Ubique Biosensor ID associated with the patient. But no patient specific information is stored in UbiqVue™ Holter Central Server, except the patient diary events. The UbiqVue™ Holter Central Server allows UbiqVue™ Web Server to access these stored ECG data with appropriate authentication via a suitable Application Specific Interface (API).

UbiqVue™ Holter Web Server Software installed in a cloud server, communicates with UbiqVue Central Server, UbiqVue Holter Web Portal, EMR (Electronic Medical Record) and stores the Biosensor ECG data by linking to appropriate patient demographic & procedure information. It also provides Biosensor, Holter Mobile App, Relay Bridge status information to UbiqVue Holter Web Portal by accessing UbiqVue Holter Center Server.

On demand (by users), UbiqVue Holter Web Server may also generate an interim raw ECG file (.EDF file format) based on the available ECG data, during the cardiac procedure. The Holter Web Server also generates the final ECG file(.EDF file format) once the cardiac procedure is completed. These raw ECG file (edf file format) generated by the Web server can be transferred (offline or online) to a compatible regulatory cleared 3rd party analysis software for doing necessary automated arrhythmia analysis (with or without manual over-read) as per the approved cardiac workflow.

UbiqVue™ Holter Web Portal is a browser-based application that provides user interface to various users of clinical facility (Admin, Nurse, Prescribing Physician, Interpreting Physician, ECG Technician, etc.) to manage Cardiac (Holter) workflow for their patients such as registering a Cardiac (Holter) procedure, linking the Biosensor ID to the procedure, entering patient demographic information, manage & configure Holter reports, view Holter Mobile App data retrieval status & Biosensor connection status.

If a compatible regulatory cleared 3rd party analysis software is integrated with the Web server, then web server could also receive the ECG analysis report (typically in .pdf format) generated by the software (with or without a manual over-read) for Interpreting Physician to view, review, interpret, eSign & approve the reports using Web portal. These finalized reports shall be available for prescribing physician to view, download and print through web portal.

8 Indications for Use

- The UbiqVue™ 2AYe Cardiac System is intended to capture, record for analysis and report both symptomatic and asymptomatic cardiac events, along with continuous electrocardiogram (ECG) information, for long-term monitoring. Following patient monitoring using the UbiqVue™ Wearable Biosensor, a comprehensive final report is generated from the entire ECG recording. Optionally, intended users may choose to generate an interim report from periodically or intermittently transferred ECG recording wirelessly from the UbiqVue™ Wearable Biosensor. Final & interim reporting is based on the beat-to-beat information extracted from the ECG recording.

- The UbiqVue™ 2AYe Cardiac system is intended for non-critical, adult population, who are 18 years of age or older, at home and in healthcare settings, who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reports are provided for review by the intended user to render a diagnosis based on their clinical judgment and experience.

9 Substantial equivalence comparison with Predicate device(s)

Comparison	Primary Predicate (K200690)	Secondary Predicate (K163512)	Subject Device
Manufacturer	LifeSignals, Inc. USA	iRhythm Technologies, Inc.	LifeSignals, Inc. USA
Product Codes	DRG, MWJ	QYX, DSH, DQK, DSI, DXH	DRG, QYX, MWJ, DXH
Regulation Classification (Primary)	21 CFR 870.2910 Class II	21 CFR 870.1025 Class II & 21 CFR 870.2800 Class II	21 CFR 870.2910 Class II
Intended use / Indications for use	The LifeSignals ECG Remote Monitoring Patch Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of Electrocardiography (ECG) and Heart Rate monitoring in home and healthcare settings. Data is transmitted wirelessly from LifeSignals Biosensor Patch to Remote Secure Server for storage and analysis. The LifeSignals ECG Remote Monitoring Patch Platform is intended for non-critical, adult population, who are 18 years of age or older. The LifeSignals ECG Remote Monitoring Patch Platform includes an ability	The Zio AT/QX ECG Monitoring System is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram (ECG) information for long-term monitoring. While continuously recording patient ECG, both patient-triggered and automatically detected arrhythmia events are transmitted to a monitoring center for reporting. After wear, a final report is generated based on beat-to-beat information from the entire ECG recording. It is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of	The UbiqVue™ 2AYe Cardiac System is intended to capture, record for analysis and report both symptomatic and asymptomatic cardiac events, along with continuous electrocardiogram (ECG) information, for long-term monitoring. Following patient monitoring using the UbiqVue™ Wearable Biosensor, a comprehensive final report is generated from the entire ECG recording. Optionally, intended users may choose to generate an interim report from periodically or intermittently transferred ECG recording wirelessly from the UbiqVue™ Wearable Biosensor. Final & interim reporting is based on the

Comparison	Primary Predicate (K200690)	Secondary Predicate (K163512)	Subject Device
	to notify healthcare professionals when Heart Rate falls outside the set limits.	breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reports are provided for review by the intended user to render a diagnosis based on clinical judgment and experience. It is not intended for use on critical care patients.	beat-to-beat information extracted from the ECG recording. The UbiqVue™ 2AYe Cardiac system is intended for non-critical, adult population, who are 18 years of age or older, at home and in healthcare settings, who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reports are provided for review by the intended user to render a diagnosis based on their clinical judgment and experience.
Intended Population	Non-critical, adult population, 18 years or older	Non-pediatric, non-critical care patient	Non-critical, adult population, 18 years or older
Intended Use Environment	Home & Healthcare settings	Home & Healthcare settings	Home & Healthcare settings
Supported Workflow	Remote Patient Monitoring, Holter, Cardiac Event Monitor, Mobile Cardiac Telemetry (through	Holter and Mobile Cardiac Telemetry	Holter, Cardiac Event Monitor, Mobile Cardiac Telemetry (through integration with another ECG analysis software)

Comparison	Primary Predicate (K200690)	Secondary Predicate (K163512)	Subject Device
	integration with another ECG analysis software)		
Biosensor			
Single Use	✓	✓ (recycle)	✓
Wear / Battery Life	03 days	14 days	8 days
Recording Format	Continuous	Continuous	Continuous
Data Storage capacity (max)	03 days	14 days	8 days
Data Transfer	Continuous or periodic during the procedure, with data buffered and transmitted when connectivity is available	Periodic during the procedure (AT) and after procedure completion (QX)	Continuous or Periodic during the procedure or after procedure completion.
Data Transfer method	Wireless	Mailed (Zio QX) Wireless (Zio AT)	Wireless
Number of ECG Channels	Two Channel	Single Channel	Two Channel
ECG Sampling Rate	244.14 Hz	200 Hz	244.14 Hz
ADC Resolution	16 bits	~15.5 bits	16 bits
Dimension	112 × 79 × 6 mm	139.7 × 55.8 × 10.6 mm	116.5 x 91.5 x 15.5 mm
Weight	24.5 g	10 g	32 g
Location of Body	Upper Left Chest	Upper Left Chest	Upper Left Chest
Battery	Zinc-air	$LiMnO_2$	$LiMnO_2$
ECG electrode	Wet Electrode (hydrogel)	Wet Electrode (hydrogel)	Wet Electrode (hydrogel)
Applied part category	Type CF	Type BF	Type CF
Defibrillation Proof	✓	✗	✓

Comparison	Primary Predicate (K200690)	Secondary Predicate (K163512)	Subject Device
HF Surgical equipment compatibility	✓	✗	✓
Communication protocol	WLAN (802.11b)	BLE (only for Zio AT)	WLAN (802.11b) & BLE (5.2)
Wireless Radio Frequency	2.4 – 2.485 GHz	2.4 – 2.485 GHz	2.4 - 2.4835 GHz
Communication Security	WPA2-PSK/AES-CCM	AES-CCM	WPA2-PSK/CCMP AES-CCM
Patient Mobile App.			
Data transferred to Server	✓	✓	✓
Symptoms & activity Recording	✓	✓	✓
ECG Analysis Software	No in-built arrhythmia analysis; intended to be used with any regulatory cleared third-party arrhythmia analysis software software.	Arrhythmia analysis software integrated into the system for Holter Report (Zio QX) Automatic Arrhythmia analysis integrated in Biosensor (Zio AT)	No in-built arrhythmia analysis; intended to be used with any regulatory cleared third-party aarrhythmia analysis software software.
Other components	Secure Server, Web UI (Portal)	Patch, Relay Device and Monitoring Center (ZEUS system)	Relay Bridge, Central Server, Web Server, Web Portal, Mobile App

Note: ✓*Feature is identical* ✗*Feature not available* - Feature Unknown

Differences and Risks associated:

- The Subject device is intended for any cardiac workflow based on integration of the third-party ECG analysis software (similar to primary predicate), while the secondary predicate device is intended for Holter and Mobile Cardiac Telemetry based on the Biosensor used. However, this change does not add any risk.

- For meeting the intended use, the secondary predicate device Zio QX patch (K163512) transfers the stored ECG data only after the end of the procedure. However, the subject device has the ability to do a periodic data transfer during the procedure through "Holter Mobile App" in addition to the option of transferring the data after end of the procedure, similar to primary predicate (K200690) and secondary predicate Zio AT patch (K163512).
    - This additional feature does not add risk, as it is verified & validated (Usability) by LifeSignals, Inc. This feature helps clinical personnel an option to generate the interim (ECG) report when required during the procedure, giving additional clinical benefits. Further, it expedites the generation of ECG file (e.g., EDF format) immediately after the end of procedure as the data is immediately retrieved.

- The Subject device has the following additional system components compared to Predicate (which may have similar components):
    - *Relay Bridge Software.* This is one of the components of UbiqVue™ 2A Multiparameter system that is cleared under K242018 (Reference Device). In Subject device this component is intended for transferring the ECG data after the end of the procedure at clinical facility by connecting one or more Biosensor at a time using Wi-Fi protocol.
    - *Web Server Software.* This is technically equivalent to Central Server, which is also one of the components of UbiqVue™ 2A Multiparameter system that is cleared under K242018 (Reference device).

  These additional system components in the subject device do not add risk as these components are either part of the already cleared system and the performance of these components are verified & validated for usability & performance.

10 Comparison with Reference device (For Biosensor Technology & Software component architecture)

Comparison	Reference Device (K242018)	Subject Device
Manufacturer	LifeSignals, Inc., USA	LifeSignals, Inc., USA
Product Codes	DRG, MHX, FLL, DQA	DRG, QYX, MWJ, DXH
Regulation Classification (Primary)	21 CFR 870.2910 Class II	*Identical*
Intended Population	Non-critical, adult population, 18 years or older	*Identical*
Intended Use Environment	Home & Healthcare settings	*Identical*
Supported Workflow	Near real-time continuous patient monitoring	Holter, Cardiac Event Monitor, Mobile Cardiac Telemetry (through integration with another ECG analysis software)
Intended use / Indications for use	The UbiqVue™ 2A Multiparameter System is a wireless remote patient monitoring system intended for use by healthcare professionals for continuous collection of physiological data at home and in healthcare settings. This shall include electrocardiography, heart rate, SpO2%, respiration rate, pulse rate, photoplethysmography waveform, skin temperature, body temperature, body posture, body motion, R-R Interval, heart rate variability (HRV) and Blood Pressure (optional). Data is transmitted wirelessly near real time from UbiqVue 2A Wearable Biosensor and 3rd party device (for Blood Pressure only) to Remote Central server for display, storage, and analysis. The UbiqVue™ 2A Multiparameter System is intended for non-critical, adult population.	The UbiqVue™ 2AYe Cardiac System is intended to capture, record for analysis and report both symptomatic and asymptomatic cardiac events, along with continuous electrocardiogram (ECG) information, for long-term monitoring. Following patient monitoring using the UbiqVue™ Wearable Biosensor, a comprehensive final report is generated from the entire ECG recording. Optionally, intended users may choose to generate an interim report from periodically or intermittently transferred ECG recording wirelessly from the UbiqVue™ Wearable Biosensor. Final & interim reporting is based on the beat-to-beat information extracted from the ECG recording.

Comparison	Reference Device (K242018)	Subject Device
	The UbiqVue™ 2A Multiparameter System shall include the ability to notify healthcare professionals through alerts when Physiological parameters fall outside the set limits, manual trigger by patient and to display multiple patient's physiological data for remote monitoring at home and with visual alarm for active monitoring at hospitals and out of hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals.	The UbiqVue™ 2AYe Cardiac system is intended for non-critical, adult population, who are 18 years of age or older, at home and in healthcare settings, who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reports are provided for review by the intended user to render a diagnosis based on their clinical judgment and experience.
Wearable Biosensor		
Single Use Device	Yes	*Identical*
ECG Electrodes	Four Integrated wet gel	*Identical*
Thermistor	For Skin temperature	***Not Applicable***
Optical Sensor	For SpO2 & PR	***Not Applicable***
Accelerometer	For Posture & Motion	*Available & but not Used*
Ambient sensor	For Body temperature	***Not Applicable***
Body contact material	Hydrogel & Long-term wear acrylic adhesive	*Identical*
Battery	Li-MnO2 (1600 mAh)	*Identical*
Applied part category	Type CF	*Identical*
Defibrillation Proof	Yes	*Identical*
HF Surgical equipment compatibility	Yes	*Identical*
MRI Safe	No	*Identical*
Communication protocol	WLAN (802.11b), BLE 5.2	*Identical*
Wireless Radio Frequency	2.4 - 2.4835 GHz	*Identical*
Communication Security	WPA2-PSK /CCMP AES-CCM 128	*Identical*
Status LED indicator	Green, Red	*Identical*

Comparison	Reference Device (K242018)	Subject Device
Patient Event Logging Button	Yes	*Identical*
Wear-life	120 hours	***192 hours***
Shelf life (claimed)	13 months	*Identical*
Length	116 x 91 x17 mm	*Identical*
Width	91 mm	*Identical*
Thickness	17 mm	**15.5 mm**
Weight	35 g	**32 g**
Patient Relay Device		
Supported OS	Android	Android & iOS
Authentication from Server	✓	✓
Data transferred to Server	✓	✓
Connectivity with Biosensor	Wi-Fi (802.11b)	BLE (5.2)
Symptom & Activity Recording	✓	✓
Relay Bridge Application		
Supported OS	Open WRT	*Identical*
Supported Hardware	Off-the Shelf Router	*Identical*
Connectivity with Biosensor	Wi-Fi (802.11b)	*Identical*
Support for Multiple Biosensor connectivity	✓	✓
Central Server Software		
Architecture	Linux based platform (including cloud-based hardware platform)	*Identical*
Data Access	Data is stored for access by Active Monitoring Portal	Data is stored for access by Web Server
Alert Notification	(Clinical, Technical, Manual)	***Not Applicable***

Comparison	Reference Device (K242018)	Subject Device
Data encryption & cybersecurity control	Conformance to guidance	*Identical*
Web Server		
Architecture	-	Equivalent to Central Server.
Data Access	-	Authorized Users of Web Portal
Web (Monitoring) Portal		
Architecture	Browser based application	*Identical*
User Interface	Designed for Multiparameter workflow	Designed for Cardiac workflow
Active Monitoring	Yes	***Not Applicable***

11 Summary of Performance Testing

Verification & Validation activities were performed on UbiqVue™ Cardiac System to demonstrate substantial equivalence to the predicate devices:

- Electrical Safety (EMT) and electromagnetic compatibility (EMC) testing were conducted on UbiqVue™ 2AYe Cardiac System with UbiqVue™ 2AYe Wearable Biosensors for conformance to *IEC 60601-1(Ed.3.2), IEC 60601-1-2 (Ed. 4.1)* and IEC *60601-1-11 (Ed. 2.1)*

- Wear-life performance of ECG quality of UbiqVue™ 2AYe Cardiac System using UbiqVue 2AYe Wearable Biosensor under normal use condition (Ambulatory use) was validated using non-randomized, on-body performance study for the wear period of 192 hours.

- Usability study was conducted on UbiqVue™ 2AYe Cardiac System for conformance to *IEC 60601-1-6 (Ed. 3.2)* and *"USFDA Guidance- Applying Human Factors and Usability Engineering to Medical Devices."*

- Wireless performance & coexistence testing conducted as per *ANSI/IEEE C63.27:2017: American National Standard for Evaluation of Wireless coexistence* on UbiqVue™ 2AYe Cardiac System.

- Software components in UbiqVue™ 2AYe Cardiac System were designed, documented, verified & validated as per the *IEC 62304: Medical device Software - Software Life Cycle Process* and USFDA *Guidance for the content of premarket submissions for Software contained in medical devices*.

- Software components in UbiqVue™ 2AYe Cardiac System were securely designed by following *IEC 81001-5-1 Health software and health IT systems safety, effectiveness and security – Activities in the product life cycl*e and USFDA guidance "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*"

- Shelf-life & Reliability testing were conducted as per MIL-STD-810H, IEC 60068-206, *RTCA DO-160* & IEC 60068-2-27 and verified on UbiqVue™ 2AYe Wearable Biosensor, as per the acceptance criteria.

- Biocompatibility testing of In-vitro cytotoxicity, skin irritation, skin sensitization and intracutaneous reactivity were conducted on UbiqVue™ 2A Wearable Biosensor (Reference Device K242018), according to *ISO 10993-1: 2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process* and submitted for the clearance. These reports are applicable for UbiqVue™ 2AYe Wearable Biosensor also. In addition to the above, Intracutaneous reactivity tests

were also conducted on UbiqVue 2AYe Wearable Biosensor and its body contact (direct and in-direct) components.

12 Conclusion

The UbiqVue™ 2AYe Cardiac System is substantially equivalent in indications for use & intended use to the legally marketed Predicate Device(s). The UbiqVue™ 2AYe Wearable Biosensor technology & all the software components architecture of UbiqVue 2AYe Cardiac System is substantially equivalent to the technology adopted in the Reference Device. Minor differences between UbiqVue™ 2AYe Cardiac System and the Predicate & Reference devices have no significant effect on safety or effectiveness, as established through various performance tests. Thus, the proposed device/system is substantially equivalent to the legally marketed predicate & reference devices.