November 15, 2023

iRhythm Technologies, Inc.
Rich Laguna
Director Qa/ra
650 Townsend Street
Suite 380
San Francisco, California 94103

Re: K163512
Trade/Device Name: Zio AT ECG Monitoring 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: QYX, DSH, DQK, DXH, DSI

Dear Rich Laguna:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 2, 2017. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jennifer Kozen, OHT2: Office of Cardiovascular Devices, 301-796-5813, jennifer.kozen@fda.hhs.gov.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 2, 2017

iRhythm Technologies, Inc.
Rich Laguna
Director of Quality & Regulatory Affairs
650 Townsend Street
Suite 380
San Francisco, CA 94103

Re: K163512
Trade/Device Name: Zio QX ECG Monitoring System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH, DQK, DXH, DSI
Dated: May 2, 2017
Received: May 3, 2017

Dear Rich Laguna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163512

Device Name
Zio® QX ECG Monitoring System

Indications for Use *(Describe)*
The Zio 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 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"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

510(k) Notification __K163512__

I. GENERAL INFORMATION [21CFR807.92(a)(1)]

Applicant:
iRhythm Technologies, Inc.
650 Townsend Street, Suite 500
San Francisco, CA 94103
U.S.A.
Phone: 415-632-5700
Fax: 415-632-5701

Contact Person:
Rich Laguna
Director Quality & Regulatory Affairs
Phone: 415-632-5749
Email: rlaguna@irhythmtech.com

Date Prepared: May 2, 2017

II. DEVICE INFORMATION [21CFR708.92(a)(2)]

Trade Name:
Zio® QX ECG Monitoring System

Generic/Common Name:
Medical magnetic tape recorder

Classification Names:
Medical magnetic tape recorder [21 CFR§870.2800]
Programmable diagnostic computer [21CFR§870.1425]
Telephone electrocardiograph transmitter and receiver [21CFR§870.2920]
Arrhythmia detector and alarm (including ST-segment measurement and alarm) [21 CFR§870.1025]

Regulatory Class:
Class II (special controls)

Product Codes:
DSH, Recorder, Magnetic Tape, Medical
DQK, Computer, Diagnostic, Programmable
DXH, Transmitters And Receivers, Electrocardiograph, Telephone
DSI, Detector And Alarm, Arrhythmia

III. PREDICATE DEVICES [21CFR708.92(a)(3)]

The following predicate devices have been selected:

- iRhythm Technologies, Inc. Zio® SR ECG Monitoring System [K143513] **(primary)**
- Medtronic, Inc. SEEQ™ Mobile Cardiac Telemetry (MCT) System [K133701]

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION [21CFR708.92(a)(4)]

The Zio® QX ECG Monitoring System consists of three key device components: (1) Zio QX Patch Recorder with Bluetooth technology, (2) Zio QX Wireless Gateway with both Bluetooth and cellular technology, and (3) the Zio ECG Utilization Service (ZEUS) System for data analysis and reporting.

The Zio® QX Patch is a non-sterile, single-patient-use ECG monitor that provides a continuous, single-channel recording in addition to asymptomatic and symptomatic data transmission for up to 14 days. The Zio® QX Patch is applied and activated by the patient. Once activated, the Patch records ECG without patient interaction, with the goal of improving patient compliance via simplicity of operation. The Zio® QX Patch, in conjunction with the Wireless Gateway and the ZEUS System, has arrhythmia auto-detection capabilities. Additionally, patients have the option of pressing a convenient trigger button which marks the continuous record and initiates the wireless transfer of a 90-second ECG strip. The wireless transfer of data is enabled by the Zio® QX Gateway, which requires Bluetooth proximity to the Patch and cellular network reception but no patient interaction to transmit to the monitoring center. The patient is encouraged to document symptomatic events in either the provided booklet, mobile medical app (iOS 9+, Android 4.4+) or via a patient website, which will support symptom-rhythm correlation in the Zio QX Report.

At the conclusion of the wear period (up to 14 days), the patient removes the Zio® QX Patch and returns it by mail to an iRhythm data processing center.

Upon receipt of both symptomatic/asymptomatic transmissions (during wear) and downloaded continuous ECG data (post wear) at iRhythm's Clinical Center (iCC), the data is processed through the ZEUS detection algorithm and delivered to the QA Tool module where the results are reviewed and/or adjusted by iRhythm's Certified Cardiographic Technicians (CCTs) for accuracy. iRhythm employed and trained Patch in-take and CCT personnel follow internal procedures for processing and are made aware of performance limitations and anomalies with both the detection algorithms and software workflow tools. All anomalies are visible to and, where appropriate, are manually corrected by iRhythm Technologies CCTs during the QA review and/or Patch Report edits. The CCT generates a final report (Zio QX Report) of the ECG findings contained within the data, thereby providing a complete ECG processing and analysis service.

Upon explicit request from a clinician responsible for the patient's healthcare, longer segments of ECG data from the continuous recording on the Patch can also be wirelessly

retrieved during the wear period. Alternatively, such periods are also available for inclusion in the final report, where the entire ECG recording is available for review and selective inclusion based on clinical relevance.

V. INDICATIONS FOR USE [21CFR708.92(a)(5)]

The Indications for Use statement for the Zio® QX ECG Monitoring System is as follows:

> The Zio 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 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.

The Indications for Use statement for the Zio® QX ECG Monitoring System differs slightly from that of the primary predicate device to address automatically detected events during wear; however, these differences do not alter the intended use of the device. Collectively, the subject device has the same intended use in cardiac arrhythmia diagnostics as the two predicate devices. Differences in the proposed Indications for Use statement are not critical to the intended use of the device, nor do they affect the safety and effectiveness of the subject device relative to the predicate devices. Therefore, the subject device can be considered substantially equivalent to the predicate devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES [21CFR708.92(a)(6)]

The proposed indications for use statement for the Zio® QX ECG Monitoring System reflect the same intended use as represented in the cleared Indications for Use statements for the predicate devices. The performance testing results demonstrate that the differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness, demonstrating that the subject device is as safe and as effective as the predicate devices. Therefore, the Zio® QX ECG Monitoring System is determined to be substantially equivalent to the predicate devices. A comparison table outlining the differences and similarities between the subject device, the Zio® QX ECG Monitoring System, and the predicate devices is provided in Table 1.

Table 1: Substantial Equivalence Summary Table

Feature	**Subject device:** iRhythm Technologies Zio® QX ECG Monitoring System [K163512]	**Primary predicate:** iRhythm Technologies Zio® SR ECG Monitoring System [K143513]	**Predicate:** Medtronic, Inc. SEEQ™ MCT System [K133701]
General Characteristics			
Classification	Class II	Class II	Class II
Classification Regulation(s)	21CFR§870.2800 21CFR§870.1425 21CFR§870.2920 21CFR§870.1025	21CFR§870.2800 21CFR§870.1425 21CFR§870.2920	21CFR§870.1025
Product Code(s)	DSH, DQK, DXH, DSI	DSH, DQK, DXH	DSI
Patient Environment	Ambulatory	Same	Same
Patient Population	Non-pediatric, non-critical care patients	Same	Non-critical care patients
Technological Characteristics			
Key System Components	1) Zio® QX Patch (wearable sensor) 2) Zio® QX Gateway (transmitter) 3) ZEUS System (software)	1) Zio® SR Patch (wearable sensor) 2) Zio® SR Gateway (transmitter) 3) ZEUS System (software)	1) SEEQ™ MCT Wearable Sensor 2) SEEQ™ MCT Transmitter 3) Software
Event Trigger	Manually by patient or automatically by arrhythmia detection algorithm	Manually by patient	Manually by patient or automatically by arrhythmia detection algorithm

VII. PERFORMANCE DATA [21CFR708.92(b)]

There are no required FDA performance standards for the Zio® QX ECG Monitoring System. All necessary performance testing was conducted on the Zio® QX ECG Monitoring System to ensure performance as intended per specifications and to support a determination of substantial equivalence to the predicate devices.

[21CFR708.92(b)(1)]:
Nonclinical testing included:

- System performance testing
- Mechanical verification testing
- Software verification testing
- Firmware verification testing
- Electrical safety and EMC testing

Automated ECG analysis performance was quantified for any claimed analysis metrics. The resulting statistics demonstrate sensitivity and positive predictivity levels which satisfy requirements.

The scope of the nonclinical testing summarized in Table 2 demonstrates that the Zio® QX ECG Monitoring System is in conformance with FDA-recognized consensus standards and FDA guidance documents.

Table 2: FDA-Recognized Consensus Standards & Guidance Document Summary

FDA #	Body	Number / Version	Title
5-70	AAMI ANSI ISO	14971:2007/(R)2010 (Corrected 4 October 2007)	Medical Devices - Applications Of Risk Management To Medical Devices
19-4	AAMI ANSI	ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
19-12	AAMI ANSI IEC	60601-1-2:2014	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
19-1	IEC	60601-1-2 Edition 3: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
19-6	IEC	60601-1-11 Edition 1.0 2010-04 [Including: Technical Corrigendum 1 (2011)]	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
3-127	AAMI ANSI IEC	60601-2-47:2012	Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic

Table 2: FDA-Recognized Consensus Standards & Guidance Document Summary

FDA #	Body	Number / Version	Title
			Systems
3-52	AAMI ANSI	EC12:2000/(R)2010	Disposable ECG Electrodes
3-118	AAMI ANSI	EC57:2012	Testing And Reporting Performance Results Of Cardiac Rhythm And ST-Segment Measurement Algorithms
N/A	U.S. FDA	October 28, 2003	Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm
N/A	U.S. FDA	October 2, 2014	Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

[21CFR708.92(b)(2)]:
No clinical testing was performed in support of this premarket notification.

[21CFR708.92(b)(3)]:
The results confirm by examination and provision of objective evidence that the design output met the design input requirements. The results of the nonclinical testing performed demonstrate that the Zio® QX ECG Monitoring System meets the requirements of established conformance standards and performance specifications necessary for its intended use and does not raise new questions of safety or effectiveness as compared to the predicate devices.

VIII. CONCLUSION

The Zio® QX ECG Monitoring System is substantially equivalent to the predicate devices.