October 30, 2024

iRhythm Technologies, Inc.
Soyini Hamit
Senior Regulatory Affairs Program Lead
699 8th Street
Suite 600
San Francisco, California 94103

Re: K240177
Trade/Device Name: Zio AT® device (A100A1001)
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, DXH, DSI
Dated: August 13, 2024
Received: August 13, 2024

Dear Soyini Hamit:

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,

Kimberly N. Crowley -S

For: Jennifer Kozen
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics, and
Monitoring Devices
OHT2: 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)*

K240177

Device Name

Zio AT® device (A100A1001)

Indications for Use *(Describe)*

The Zio AT device is intended to capture and transmit symptomatic and asymptomatic cardiac events and record continuous electrocardiogram (ECG) data for long-term monitoring. 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. 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.***

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# 510(k) Notification K240177

## I. General Information

**Applicant:**

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Sr. Director, Regulatory Affairs

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**Date Prepared:** October 21, 2024

## II. Device Information

**Trade Name:**

Zio AT®

**Generic/Common Name:**

Outpatient Cardiac Telemetry

**Classification Name**

Medical magnetic tape recorder [21CFR§870.2800]

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:**

QYX, Outpatient Cardiac Telemetry

DSH, Recorder, Magnetic Tape, Medical

DXH, Transmitters and Receivers, Electrocardiograph, Telephone

## III. Predicate Devices

The following predicate device has been selected:

- iRhythm Technologies, Inc. Zio® AT ECG Monitoring Device [K240029]

## IV. Device Description

The Zio AT® Electrocardiogram (ECG) Monitoring System is intended for continuous, long-term monitoring of a patient's ECG data with the ability to provide symptomatic and asymptomatic transmissions of potential arrhythmias during wear time.

The Zio AT ECG Monitoring System enables ambulatory Mobile Cardiac Telemetry (MCT) services for non-critical care patients by providing the following devices for use.

The Zio AT device consists of the Zio AT patch and Zio AT wireless gateway**:**

- Zio AT Patch

  The Zio AT patch is a single-use ECG monitor applied to the patient's chest, in-clinic or at home, and worn for up to 14 days without any required patient interaction for maintenance, such as replacing or charging a battery.

  The patch continuously records ECG data and transmits symptomatic and asymptomatic cardiac events through the Zio AT wireless gateway during the wear period.

  After the wear period concludes, the patient removes and returns the patch to the monitoring center, an Independent Diagnostic Testing Facility (IDTF), for analysis and end-of-wear reporting.

- Zio AT Wireless Gateway

  The Zio AT wireless gateway securely receives ECG data from the Zio AT patch using Bluetooth technology. The gateway securely transmits ECG data through cellular technology for subsequent processing.

The Zio AT device is designed to be used with the interoperable Zio ECG Utilization Service (ZEUS) SaMD which provides an arrhythmia detection algorithm for analysis and reporting.

## V. Indications for Use

The Indications for Use statement for the Zio AT device is as follows:

The Zio AT device is intended to capture and transmit symptomatic and asymptomatic cardiac events and record continuous electrocardiogram (ECG) data for long-term monitoring. 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. It is not intended for use on critical care patients.

**VI. Comparison of Technological Characteristics with Predicate Devices (Substantial Equivalence)**

The subject and predicate device have the same intended use and similar indications for use statements. The difference in technological characteristics between the subject and predicate Zio AT device are minor and do not raise different questions of safety and effectiveness. Bench testing (non-clinical tests) performed on the subject Zio AT device using the same test methodologies as the predicate, did not identify any issues and further confirm that the device performs as intended.

A comparison table outlining the differences and similarities between the subject device, the Zio AT device, and the predicate device is provided in **Table 1**.

**Table 1: Substantial Equivalence Summary Table**

| **Feature** | **Subject Device:** Zio AT device | **Predicate Device:** Zio AT ECG Monitoring System (K240029) |
|---|---|---|
| **General Characteristics** | | |
| Classification | Class II | Class II |
| Classification Regulations | 21CFR§870.2800; 21CFR§870.2920; 21CFR§870.1025 | Same |
| Product Code | QYX, DSH, DXH, DSI | Same |
| Indications for Use | The Zio AT device is intended to capture and transmit symptomatic and asymptomatic cardiac events and record continuous electrocardiogram (ECG) data for long-term monitoring. 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. It is not intended for use on critical care patients. | Same |
| Patient Environment | In clinic; At home | Same |
| Patient Population | 18 years and older, non-critical care, ambulatory patients | Same |
| **Technological Characteristics** | | |
| Key System Components | 1. Zio AT Patch<br>2. Zio AT Gateway | Same |

| | | |
|---|---|---|
| Event Trigger | • Patient-triggered (Button press by the patient for symptomatic events)<br>• Auto-trigger (Asymptomatic) | Same |
| System Communication /Transmission | 1. Short range RF (between patch and gateway)<br>2. Cellular RF, LTE (between gateway and ZEUS System)<br>3. Manual/computer interface (between patch and ZEUS System) | Same |

## VII. Performance Data

There are no required FDA performance standards for the Zio AT device. All necessary performance testing was conducted on the Zio AT device to ensure performance as intended per specifications and to support a determination of substantial equivalence to the predicate device.

Nonclinical testing included:

- System performance testing
- Biocompatibility testing
- Firmware verification testing
- Electrical safety and EMC testing

The scope of the nonclinical testing summarized in **Table 2** demonstrates that the Zio AT device 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 |
|---|---|---|---|
| 19-4 | IEC | 60601-1:2005/A1:2012 | General requirements for basic safety and essential performance for Medical electrical equipment |
| 19-8 | IEC | 60601-1-2:2014 | General requirements for safety – Collateral standard: Electromagnetic compatibility—Requirements and tests |
| 19-36 | IEC | 60601-1-2:2014+A1:2020 | General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility Requirements and tests |
| 5-132 | IEC | 60601-1-6:2010/ A1:2013+A2:2020 | General requirements for safety – Collateral standard: Usability |
| 5-76 | IEC | 60601-1-8:2006/A1:2012 | General requirements for safety – Collateral standard: General requirements, tests and |

| | | | |
|---|---|---|---|
| | | | guidance for alarm systems in medical electrical equipment |
| 2-258 | ISO | 10993-1:2018 | Biological evaluation of medical devices – Evaluation and testing |
| 2-245 | ISO | 10993-5:2009 | Biological evaluation of medical devices-Part 5:Tests for in vitro cytotoxicity |
| 5-134 | ISO | 15223-1:2021 (Fourth Edition) | Symbols to be used with medical device labels, labeling and information to be supplied-Part 1 General Requirements |
| 5-125 | ISO | 14971:2019 | Medical devices – Application of risk management to medical devices |
| 5-135 | ISO | 20417:2021 | Medical devices – Information to be supplied by the Manufacturer |
| 5-129 | IEC | 62366-1:2015/A1:2020 | Medical device – Application of usability engineering to medical devices |
| 13-79 | IEC | 62304:2006 Ed. 1.1 2015 | Medical device software – Software lifecycle processes |
| 3-155 | IEC | 60601-2-47:2012 | Medical electrical equipment -- Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems |
| N/A | FDA | Class II Special Controls Guidance Document for Industry and FDA Staff | Arrhythmia Detector and Alarm (issued October 28, 2003) |
| N/A | FDA | Guidance for Industry and FDA Staff | The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] (issued July 28, 2014) |
| N/A | FDA | Guidance for Industry and FDA Staff | Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (issued September 27, 2023) |
| N/A | FDA | Guidance for Industry and FDA Staff | Content of Premarket Submissions for Device Software Functions (issued June 14, 2023) |

## VIII. Clinical Testing in Support of Substantial Equivalence Determination

No clinical testing was performed in support of this premarket notification.

## IX. Conclusion

The results of the nonclinical testing performed demonstrate that the Zio AT device 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 device. The Zio AT device is substantially equivalent to the predicate device.