August 15, 2025

iRhythm Technologies, Inc.
Kiran Sorathia
Staff Regulatory Affairs Specialist
699 8th Street
Suite 600
San Francisco, California 94103

Re: K243650
Trade/Device Name: Zio® monitor (DFG0001)
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: November 26, 2024
Received: July 15, 2025

Dear Kiran Sorathia:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243650

Device Name
Zio® monitor

Indications for Use *(Describe)*
The Zio monitor is a prescription-only, single-use, ECG monitor that continuously records data for up to 14 days.

It is indicated for use on patients, 18 years and older, who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue, or anxiety.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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) Notification K243650

I. General Information

Applicant:
iRhythm Technologies, Inc.
699 8th Street, Suite 600
San Francisco, CA 94103 USA
Phone: 415-632-5700
Fax: 415-632-5701

Contact Person:
Kiran Sorathia
Staff Regulatory Affairs Specialist
Phone: 469-420-0310
Email: kiran.sorathia@irhythmtech.com

Alternate Contact Person:
Soyini Hamit
Sr. Manager, Regulatory Affairs
Phone: 310-571-5418
Email: soyini.hamit@irhythmtech.com

Date Prepared: November 26, 2024

II. Device Information

Trade Name:
Zio® monitor

Generic/Common Name:
Medical magnetic tape recorder

Classification Names:
Medical magnetic tape recorder [21CFR§870.2800]

Regulatory Class:
Class II (Special Controls)

Product Codes:
DSH, Recorder, Magnetic Tape, Medical

III. Predicate Devices

The following predicate device has been selected:

- iRhythm Technologies, Inc. Zio® monitor[K202359]

The following reference device has been selected:

- iRhythm Technologies, Inc. Zio AT® Device [K240177]

IV. Device Description

The Zio monitor is a non-sterile, single-use, continuously recording, long-term ambulatory ECG monitor that is adhered to a patient's left pectoral region in a modified Lead II orientation. The goal of the Zio monitor is to help physicians initiate long-term, patient-compliant ECG monitoring utilizing proprietary technology. The Zio monitor is applied and activated by the patient at home or at a clinic. Once activated, the device provides continuous, uninterrupted ECG recording into memory with minimal patient interaction. There is a button on the surface of the Zio monitor, which serves to activate the device and may be pressed by the patient during wear to indicate when he or she is experiencing a symptom. Additionally, there is a surface LED light that blinks green to confirm proper activation or that the device is working, and orange to indicate loss of connection with the skin or the presence of error conditions.

The Zio monitor utilizes firmware that captures single-channel ECG data into memory, there is no wireless transmission of data during the wear period of the device. After the prescribed monitoring period is complete, the Zio monitor is returned to iRhythm where the ECG data is then analyzed and annotated by the ZEUS System (K222389). ECG data is then presented to the Qualified Cardiac Technicians (QCT) at the Independent Diagnostic Testing Facility (IDTF) for review and subsequent creation and posting of the end-of-wear report with preliminary findings. Zio monitor device is not intended for real-time patient monitoring.

V. Indications for Use

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

The Zio monitor is a prescription-only, single-use, ECG monitor that continuously records data for up to 14 days.

It is indicated for use on patients, 18 years and older, who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue, or anxiety.

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 differences in technological characteristics between the subject and predicate Zio monitor device are minor and do not raise different questions of safety and effectiveness.

Traditional 510(k): 510(k) Summary

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

Table 1: Substantial Equivalence Summary Table

Feature	**Subject Device:** Zio monitor device	**Predicate Device:** Zio monitor device (K202359)	**Reference Device:** Zio AT® Device (K240177)
General Characteristics			
Classification	Class II	Same	Same
Classification Regulations	21CFR§870.2800;	Same	21CFR§870.2800; 21CFR§870.2920; 21CFR§870.1025
Product Code	DSH	Same	QYX, DSH, DXH, DSI
Indications for Use	The Zio monitor is a prescription-only, single-use, ECG monitor that continuously records data for up to 14 days. It is indicated for use on patients, 18 years and older, who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue, or anxiety.	The Zio monitor is a prescription-only, single-patient-use ECG monitor that continuously records data for up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue or anxiety	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.
Patient Environment	Ambulatory	Same	Same
Patient Population	18 years and older, non-critical care, ambulatory patients	Same	Same
Technological Characteristics			
Key System Components	Zio monitor	Same	1. Zio AT Patch 2. Gateway

Event Trigger	Patient-triggered (Button press by the patient for symptomatic events)	Same	• Patient-triggered (Button press by the patient for symptomatic events) • Auto-trigger (Asymptomatic)
Fundamental Theory of Operation	An adherent, patient-worn device containing sensors collects patient ECG data	Same	An adherent, patient-worn device (patch) containing sensors, which collects and transmits patient ECG data in conjunction with a bridge (gateway) that receives data from this sensor device and transmits data to a server (ZEUS System, K222389) where data is then analyzed with software and provided to an IDTF Qualified Cardiac Technician.
Information Display/Storage	Data not displayed to use on device in real-time; data stored on device for transmission and/or retrieval	Same	Data not displayed to user on device in real-time; data stored on device for patient triggered or asymptomatic routine transmission and/or retrieval at the end of wear
Performance Characteristics			
Weight	10.0g	Same	Patch: 24.7 grams Gateway: 158 grams
Dimensions	5.5 x 2.2 x 0.4in	Same	Patch: 5.2 x 2.0 x 0.5 in. Gateway: 6.2 x 3.4 x 0.8 in.
Material	Polycarbonate with ESD Filler	Same	Same
Adhesive Surface Area	~6.85 in2	Same	Same
Primary Adhesive	Hydrocolloid	Same	Same
Border Adhesive	Acrylic Adhesive	Same	Same
Adhesive Construct	Polyethylene and Polyurethane	Same	Same
ECG Channels	1 channel	Same	Same
Memory Capacity	21 days	Same	14 days

Traditional 510(k): 510(k) Summary

Recording Format	Continuous	Same	Same
Service Life	Up to 14 days	Same	Same
Shelf Life	6 months	Same	Same
Out-of-Package Shelf Life	Use upon opening	Same	Same
Medical Equipment Type	BF Applied Part	Same	Same
ECG Frequency Response	0.67Hz to 40Hz	Same	Same
ECG Input Impedance	≥ 10 MΩ	Same	Same
ECG Differential Range	±1.65 mV	Same	Same
ECG A/D Sampling Rate	200 Hz	Same	Same
ECG Resolution	15.5 bits	Same	10 bits
Battery Type	1x Lithium Manganese Dioxide Coin Cell (non-rechargeable)	Same	Patch: 2 Lithium Manganese Dioxide Coin Cells Gateway: 1 Lithium Polymer Cell
Battery Life (Monitoring)	21 days	Same	Patch: 14 days; Gateway: 14 days
Operational Temperature	41 to 104 degrees F	Same	Same
Operational Altitude	-1,000 to 10,000ft	Same	Same
Operational & Storage Humidity	10% to 95% (non-condensing)	Same	Same
Shipping (short-term storage) Temperature	-4 to 104 degrees F	Same	Same
Long-term Storage Temperature	64 to 80 degrees F	Same	55 to 85 degrees F
Storage Altitude	1,000 to 14,000ft	Same	Same
Patch IP Classification	IPx7	Same	Patch: IP24 Gateway: IP22

VII. Performance Data

There are no required FDA performance standards for the Zio monitor device. All necessary performance testing was conducted on the Zio monitor 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
- Human Factors testing

Additional analysis was conducted regarding a new failure mode found for IR sensitivity. This testing compared the Zio monitor device to that of the Zio AT and determined that the analyzable time between the two devices are equivalent in performance.

The scope of the nonclinical testing summarized in **Table 2** demonstrates that the Zio monitor 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
19-49	IEC	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	General requirements for basic safety and essential performance for Medical electrical equipment
19-38	IEC	60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	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
19-36	IEC	60601-1-2:2014 [Including AMD 1:2021]	General requirements for safety – Collateral standard: Electromagnetic compatibility— Requirements and tests
5-132	IEC	60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	General requirements for safety – Collateral standard: Usability
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
2-174	ISO	10993-10:2013	Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization
2-255	ISO	10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
2-291	ISO	10993-23:2021	Biological evaluation of medical devices-Part 5:Tests for in vitro cytotoxicity
5-125	ISO	14971:2019	Medical devices – Application of risk management to medical devices
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	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 monitor 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 monitor device is substantially equivalent to the predicate device.