May 21, 2021

iRhythm Technologies, Inc.
Rey Jacinto
Sr. Manager, Regulatory Affairs
699 8th Street
San Francisco, California 94103

Re: K202359
Trade/Device Name: Zio Monitor
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH, MWJ
Dated: May 20, 2021
Received: May 21, 2021

Dear Rey Jacinto:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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 Shih 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)*
K202359

Device Name
Zio® Monitor

Indications for Use *(Describe)*
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.

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 K202359

I. General Information

Applicant:

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Date Prepared: August 17, 2021

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

Product Codes:

DSH, Recorder, Magnetic Tape, Medical

MWJ, Electrocardiograph, Ambulatory (Without Analysis)

III. Predicate Devices

The following predicate device has been selected:

– iRhythm Technologies, Inc. Zio® XT Patch [K121319]

The following reference device has been selected:
– iRhythm Technologies, Inc. Zio® AT Patch [K181502]

IV. Indications for Use

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

> 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.

V. Device Description

The Zio monitor is a non-sterile, single-patient-use, 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.

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

The Indications for Use statement for the Zio monitor are substantially equivalent to the cleared Indications for Use statement of the predicate device. Differences in the phrasing of the proposed Indications for Use statement from the predicate device are not critical to the intended use of the device, nor do they affect the substantial equivalence of the subject device relative to the predicate device (Section 12.3.2). Therefore, the subject device can be considered substantially equivalent to the predicate device.

The performance testing results demonstrate that the differences in the technological characteristics (i.e. reduced weight and power) between the devices do not raise any

new issues of safety or efficacy as compared to the predicate. Therefore, the Zio monitor is determined to be substantially equivalent to the predicate device.

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

Table 1. Substantial Equivalence Summary Table

Feature	**Subject Device: Zio® monitor**	**Predicate Device: Zio® XT Patch**
General Characteristics		
Classification	Class II: 21CFR870.2800	Same
Product Code	DSH MWJ	DSH
Patient Environment	Ambulatory	Same
Patient Population	Non-pediatric, non-critical care patients	Same
Technological Characteristics		
Event Trigger	Manually by patient	Same
Size	The Zio Monitor has a reduced form factor	

VII. Performance Data

There are no required FDA performance standards for the Zio monitor. 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:

- Mechanical verification 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 monitor 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
5-40	AAMI ANSI ISO	14971:2012(R)2010 (Corrected 4 October 2017)	Medical Devices – Applications Of Risk Management To Medical Devices
19-4	AAMI ANSI	ES 60601-1:2005/(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)
19-8	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
19-6	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 Systems
2-220	ISO	10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
2-245	ISO	10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
2-174	ISO	10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
13-79	IEC	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes

5-113	ASTM	D7386-16	Standard Practice for Performance Testing of Packages for Single Delivery Systems
5-99	ASTM	D4332-14	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

VIII. Clinical Testing in Support of Substantial Equivalence Determination

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

IX. Conclusion

The results confirm by examination and provision of objective evidence that the design outputs met the design input requirements. The results of the nonclinical testing performed demonstrate that the Zio monitor 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. The Zio monitor is substantially equivalent to the predicate device.