iRhythm Technologies Receives FDA 510(k) Clearance for Design Modifications to Its Zio® AT Device

October 30, 2024

Zio AT device, along with the Zio ECG Utilization Software (ZEUS) (K222389), enables the provision of ambulatory Mobile Cardiac Telemetry (MCT) monitoring service for non-critical care patients

FDA 510(k)-cleared enhancements will be available in 2025

SAN FRANCISCO, Oct. 30, 2024 (GLOBE NEWSWIRE) -- iRhythm Technologies, Inc. (NASDAQ:IRTC), a leading digital health care company focused on creating trusted solutions that detect, predict, and prevent disease, announced today that the U.S. Food and Drug Administration (FDA) has granted clearance for its 510(k) submission related to design modifications and labeling updates for the Zio AT device. Zio AT remains commercially available on the market to ship to customers in the United States, and product enhancements subject to this 510(k) clearance will be available in 2025.

“This clearance is related to enhancements to our Zio AT product, including design features and labeling updates intended to address areas of concern specific to Zio AT that were noted in a 2023 FDA warning letter to the Company,” said Quentin Blackford, iRhythm President and Chief Executive Officer. “We believe these features that were subject to this clearance advance our technology for the benefit of patients, physicians, and healthcare systems who rely on our Zio AT services. At all times, we remain committed to patient safety, physician trust in Zio AT’s clinical performance, service quality, and regulatory compliance.”

About the Zio AT System

The Zio AT device is a prescription-only outpatient cardiac telemetry device, commonly referred to as a mobile cardiac telemetry device, which is used for the provision of our mobile cardiac telemetry (MCT) services. The Zio AT system consists of: the Zio AT patch, an ECG monitor that continuously records ECG data for up to 14 days; the wireless gateway that provides connectivity between the Zio AT patch and the Zio ECG Utilization Software (ZEUS) to transmit data during the wear period; and ZEUS, iRhythm’s deep-learning algorithm that analyzes cardiac events transmitted by the Zio AT patch and gateway. The Zio AT services provide event transmission reports during wear and a comprehensive end-of-wear report[1-4] with preliminary findings to the treating medical professional for final clinical decisions. The Zio AT services are provided by iRhythm’s independent diagnostic testing facilities located in San Francisco, California, Deerfield, Illinois and Houston, Texas.

Zio Services’ Clinically Proven Performance

The value of the Zio service has been demonstrated in over 100 original scientific research manuscripts[5]. Zio AT’s patient-centered design enables high patient compliance and analyzable time with minimal noise or artifact[6-8], and real-world data shows an impressive 98% patient compliance[9], in part thanks to Zio AT’s zero required patient manipulations. Furthermore, physicians agree with the Zio service's comprehensive end-of-wear report 99% of the time[10-11].

About iRhythm Technologies, Inc.
iRhythm is a leading digital health care company that creates trusted solutions that detect, predict, and prevent disease. Combining wearable biosensors and cloud-based data analytics with powerful proprietary algorithms, iRhythm distills data from millions of heartbeats[12] into clinically actionable information. Through a relentless focus on patient care, iRhythm’s vision is to deliver better data, better insights, and better health for all. To learn more about iRhythm, including its portfolio of Zio products and services, please visit irhythmtech.com.

Zio AT 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.

Contraindications

- Do not use the Zio AT device for patients with symptomatic episodes where variations in cardiac performance could result in immediate danger to the patient or when real-time or in-patient monitoring should be prescribed.
- Do not use the Zio AT device for patients with known history of life-threatening arrhythmias.
- Do not use the Zio AT device in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI.
- Do not use the Zio AT device on patients with a neuro-stimulator, as it may disrupt the quality of ECG data.
- Do not use the Zio AT device on patients who do not have the competency to wear the device for the prescribed monitoring period.

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1. Zio AT Clinical Reference Manual. iRhythm Technologies, 2022.
2. Continuous, uninterrupted refers to the recording of ECG data. Zio AT Gateway transmissions may be impacted by a variety of factors. See Product Labeling for more information.
3. Zio AT is contraindicated for critical care patients.
4. Do not use Zio AT for patients with symptomatic episodes where variations in cardiac performance could result in immediate danger to the patient or when real-time or in-patient monitoring should be prescribed. Refer to the Zio AT labeling and Clinical Reference Manual for full contraindications.
5. Data on file. iRhythm Technologies, 2023.
6. Data on file. iRhythm Technologies, 2022-2023.
7. Zio XT Clinical Reference Manual. iRhythm Technologies, 2019.
8. Zio monitor Instructions for Use. iRhythm Technologies, 2023.
9. Zio AT Clinical Reference Manual. iRhythm Technologies, 2022.
10. Data on file. iRhythm Technologies, 2021-2022.
11. Based on a review of all online Zio XT, Zio monitor, and Zio AT end-of-wear reports. Data on file. iRhythm Technologies, 2023.
12. Based on the US and UK data using Zio ECG monitors. Data on file. iRhythm Technologies, 2023.

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