February 15, 2023

iRhythm Technologies, Inc.
Vishal Kanani
Senior Regulatory Affairs Program Lead
699 8th Street
San Francisco, California 94103

Re: K222389
Trade/Device Name: ZEUS System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DXH, DSI
Dated: January 13, 2023
Received: January 17, 2023

Dear Vishal Kanani:

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,

for Shruti N. Mistry -S

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)*
K222389

Device Name
ZEUS System

Indications for Use *(Describe)*
The device is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring. After wear, ECG data from compatible monitoring devices is processed and analyzed by the ZEUS System. A final report is generated on the beat-to-beat information from the entire ECG recording. For the Zio AT service, the ZEUS System supports the capture and analysis of automatically-detected arrhythmia events, as well as the analysis of uploaded patient-triggered events.

The ZEUS System 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 and patients who are asymptomatic. 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.

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510(k) Notification K222389

I. General Information

Applicant:
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San Francisco, CA 94103 USA
Phone: 415-632-5700
Fax: 415-632-5701

Contact Person:
Vishal Kanani
Manager, Regulatory Affairs
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Email: vishal.kanani@irhythmtech.com

Date Prepared: July 29, 2022

II. Device Information

Trade Name:
ZEUS System

Generic/Common Name:
Programmable diagnostic computer

Classification Names:

- Programmable diagnostic computer [21CFR§870.1425]
- Arrhythmia detector and alarm (including ST-segment measurement and alarm) [21CFR§870.1025]
- Telephone electrographic transmitter and receiver [21CFR§870.2920]

Regulatory Class:
Class II (Special controls)

Product Codes:

- DQK, Computer, Diagnostic, Programmable
- DSI, Detector and Alarm, Arrhythmia
- DXH, Transmitters and Receivers, Electrocardiographic, Telephone

III. Predicate Devices

The following predicate devices have been selected:

- **Primary Predicate**: iRhythm Technologies, Inc. Zio® ECG Utilization Service (ZEUS) System [K202527]

IV. Indications for Use

The Indications for Use statement for the subject ZEUS System is as follows:

The device is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring. After wear, ECG data from compatible monitoring devices is processed and analyzed by the ZEUS System. A final report is generated on the beat-to-beat information from the entire ECG recording. For the Zio AT service, the ZEUS System supports the capture and analysis of automatically-detected arrhythmia events, as well as the analysis of uploaded patient-triggered events.

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V. Device Description

The Zio® Service consists of single-patient-use monitoring devices and the Zio ECG Utilization Software (ZEUS) System, the subject device of this submission, for analysis and reporting of cardiac information derived from ECG data. The ZEUS System is a software system consisting of a collection of software modules designed to store and analyze data from compatible cardiac monitoring devices to curate a report of preliminary findings intended for use by clinicians as an aid in arrhythmia diagnosis and management.

The subject ZEUS System utilizes an artificial intelligence (AI) AI-based AutoTrigger Engine (ATE) software application for processing requests originating from the Gateway Service as part of the Zio AT system enabling asymptomatic ECG triggers, and AI-based ECG Analysis Software (ECGDL) to generate the initial ECG-based cardiac information.

The output of ECG Analysis Software of the ZEUS System is used by Certified Cardiographic Technicians (CCTs) prior to publishing the cardiac information in the patient report and is not utilized directly by the prescribing clinician or patient. The reported cardiac information includes beats, ectopic runs, ECG segments, rhythms, and heart rate measurements. Recorded ECG is processed by an automated ECG analysis platform; results are quality reviewed by CCTs, findings and associated ECG are captured in a report provided to clinicians via a secure website. For the Zio® AT Patch/Gateway, the ZEUS System provides capabilities to automatically detect clinically actionable arrhythmia during the monitoring period, as well as receive baseline, scheduled, symptomatic, and asymptomatic transmissions.

The subject of this 510(k) are proposed software modifications to the ZEUS System to allow AF/AFL burden estimate reporting in the daily reports. In addition, software modifications were made to the ECGDL software of the ZEUS System to target modest performance improvements.

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

The subject ZEUS System has the same intended use as the predicate devices. The differences in the technological characteristics between the subject and predicate devices do not raise any issues of safety or efficacy as the fundamental scientific technology and intended use is unchanged. Thus, the ZEUS System is considered substantially equivalent to the predicate device.

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

Table 1: Substantial Equivalence Summary Table

Feature	Subject Device: ZEUS System	Primary Predicate Device: ZEUS System (K202527)
Manufacturer	iRhythm Technologies, Inc.	Identical
Classification	Class II	Identical
Product Code	**Classification Product Code**: DQK **Subsequent Product Codes**: DSI, DXH	Identical
Review Panel	Cardiovascular	Identical
Prescription/OTC	Prescription	Identical
Rhythm Detection Algorithm	ECGDL	Identical
Beat Detection	ECGDL	Same
Interoperability	• Zio XT Patch • Zio AT Patch • Zio Monitor	Identical
AF Burden Reporting	• Final Report • Daily Report (AF Burden Estimates)	• Final Report

VII. Performance Data

Safety and performance of the subject ZEUS System has been evaluated and verified in accordance with design specifications and to support a determination of substantial equivalence to the predicate device.

The design verification and validation testing performed on the subject device demonstrates that the subject ZEUS System is in conformance with FDA-recognized consensus standards and FDA guidance documents as highlighted in **Table 2**.

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 – Application of Risk Management to Medical Devices
13-79	IEC	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical Device Software - Software Life Cycle Processes
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
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 2, 2014	Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
N/A	U.S. FDA	May 5, 2005	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
N/A	U.S. FDA	September 6, 2017	Design Considerations and Premarket Submission Recommendations for Interoperable
N/A	U.S. FDA	July 2014	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

The nonclinical verification and performance test results established that the device meets its design requirements and intended use, that the design differences with the cleared device do not raise new questions of safety and efficacy. During development, potential hazards were evaluated and controlled by risk management activities, including risk analysis, risk mitigation, verification and benefit-risk analysis. The verification and validation testing demonstrate that the device meets all predetermined specifications.

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 evaluation and provision of objective evidence that the design outputs met the design input requirements. The results of the nonclinical testing performed demonstrate that the subject ZEUS 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 device. The subject ZEUS System is substantially equivalent to its predicate device.