May 29, 2026

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

Re: K252859
Trade/Device Name: ZEUS Platform (FG0501US)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: May 4, 2026
Received: May 4, 2026

Dear Brittany Davis:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252859

Please provide the device trade name(s).

ZEUS Platform (FG0501US)

Please provide your Indications for Use below.

The Zio ECG Utilization Software (ZEUS) Platform is intended to process, store, and analyze electrocardiogram (ECG) recordings captured from a compatible ECG monitor, including automatically detected arrhythmia events and patient-triggered events.

The ZEUS Platform also allows for review of the analyzed data and, subsequently, report generation.

Interpretation of the analyzed ECG data and the associated diagnosis is the responsibility of the prescribing or treating healthcare professional.

The ZEUS Platform is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety.

The ZEUS Platform is not intended for detection or notification of hemodynamically unstable or life-threatening arrhythmias or cardiac events requiring urgent medical response. It is not intended for patients at elevated risk of serious cardiovascular events that would require immediate intervention.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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: Brittany Davis
Staff Regulatory Affairs Specialist
Phone: 415-757-3012
Email: brittany.davis@irhythmtech.com

Date Prepared: May 4, 2026

II. Device Information

Trade Name: ZEUS Platform

Generic/Common Name: Programmable diagnostic computer

Classification Names: Programmable diagnostic computer [21CFR§870.1425]

Regulatory Class: Class II

Product Codes: DQK, Computer, Diagnostic, Programmable

III. Predicate Devices

The following predicate device has been selected:

- iRhythm Technologies, Inc. Zio® ECG Utilization Software (ZEUS) System [K222389]

IV. Indications for Use

The Indications for Use statement for the ZEUS Platform is as follows:

The Zio ECG Utilization Software (ZEUS) Platform is intended to process, store, and analyze electrocardiogram (ECG) recordings captured from a compatible ECG monitor, including automatically detected arrhythmia events and patient-triggered events.

The ZEUS Platform also allows for review of the analyzed data and, subsequently, report generation.

Interpretation of the analyzed ECG data and the associated diagnosis is the responsibility of the prescribing or treating healthcare professional.

The ZEUS Platform is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety.

The ZEUS Platform is not intended for detection or notification of hemodynamically unstable or life-threatening arrhythmias or cardiac events requiring urgent medical response. It is not intended for patients at elevated risk of serious cardiovascular events that would require immediate intervention.

V. Device Description

ZEUS Platform is a Software as a Medical Device (SaMD) consisting of a collection of software modules intended to process, store and analyze electrocardiogram (ECG) recordings captured from compatible Zio ECG monitoring devices, including automatically detected arrhythmia events and patient-triggered events. ZEUS Platform also enables Qualified Cardiac Technicians (QCTs) to review and edit ECG data after algorithm analysis and facilitate report generation. Reports curated with preliminary findings are intended for use by clinicians as an aid to arrhythmia diagnosis and management.

ZEUS Platform utilizes a deep-learned, artificial intelligence-based ECG analysis software module present in both the predicate and subject devices. It is intended to analyze both ECG transmissions during wear and full ECG recordings post-wear captured by all compatible Zio ECG monitoring devices. As a part of the analysis, the ECGDL will identify and annotate beats, beat types, ectopic runs, and rhythms/artifact present in the ECG data.

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

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

Category	Subject Device	Predicate Device (K222389)
Device Name	ZEUS Platform	ZEUS System
Manufacturer	iRhythm Technologies, Inc.	Identical
Classification	Class II	Class II (Special controls)
Product Code	• Classification Product Code: DQK	• Classification Product Code: DQK • Subsequent Product Codes: DSI, DXH
Review Panel	Cardiovascular	Identical
Prescription/OTC	Prescription	Identical
Indications for use statement	The Zio ECG Utilization Software (ZEUS) Platform is intended to process, store, and analyze electrocardiogram (ECG) recordings captured from a compatible ECG monitor, including automatically detected arrhythmia events and patient-triggered events. The ZEUS Platform also allows for review of the analyzed data and, subsequently, report generation. Interpretation of the analyzed ECG data and the associated diagnosis is the responsibility of the prescribing or treating healthcare professional. The ZEUS Platform is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from symptoms such as palpitations, shortness of breath, dizziness, light-headedness, presyncope, syncope, fatigue, or anxiety. The ZEUS Platform is not intended for detection or notification of hemodynamically unstable or life-threatening arrhythmias or cardiac events requiring urgent medical	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.

Category	Subject Device	Predicate Device (K222389)
	response. It is not intended for patients at elevated risk of serious cardiovascular events that would require immediate intervention.	
Principle functionality	• ECG analysis • Post-wear reporting • Enabling QCT review	• ECG analysis • Post-wear reporting • Enabling QCT review • During wear arrhythmia detection and reporting
Interoperability	• Zio XT device • Zio monitor device • Zio AT device	• Zio XT device • Zio monitor device • Zio AT device
Rhythm detection algorithm	• ECGDLv2 (transmissions) • ECGDLv3 (post-wear)	• ECGDLv2 (transmissions and post-wear) • AutoTrigger Engine
Beat detection	ECGDL • QRS Complex • Supraventricular Beat (S Beat) • Ventricular Beat (V Beat) • Supraventricular Ectopic (SVE) Couplet • Supraventricular Ectopic (SVE) Triplet • Ventricular Ectopic (VE) Couplet • Ventricular Ectopic (VE) Triplet	• Identical
Rhythm detection	ECGDL • Pause ≥3 seconds • Ventricular fibrillation • Atrial fibrillation/flutter • Complete heart block • Second degree AV block-type II • Sinus rhythm • Supraventricular tachycardia • Ventricular bigeminy	• Identical

Category	Subject Device	Predicate Device (K222389)
	• Ventricular tachycardia • Ventricular trigeminy • Second degree AV block-type I (Wenckebach) • Ectopic atrial rhythm • Junctional rhythm • Idioventricular rhythm	

VII. Performance Data

Safety and performance of the subject ZEUS Platform 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 Platform 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
5-125	ANSI AAMI ISO	14971: 2019	Medical devices ─ Application of risk management to medical devices
13-79	ANSI AAMI IEC	62304:2006/A1:2016	Medical device software ─ Software lifecycle processes
3-155	ANSI AAMI IEC	60601-2-47: 2012/(R)2016	Medical electrical equipment -- Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
3-118	ANSI AAMI	EC57:2012	Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
5-134	ISO	15223-1 Fourth edition 2021-07	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
5-129	ANSI AAMI IEC	62366-1: 2015+AMD1:2020 (Consolidated Text)	Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
5-132	IEC	60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

FDA#	Body	Number/Version	Title
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	Content of Premarket Submissions for Device Software Functions (issued June 14, 2023)
N/A	FDA	Guidance for Industry and FDA Staff	General Principles of Software Validation (issued January 11, 2002)
N/A	FDA	Guidance for Industry and FDA Staff	Multiple Function Device Products: Policy and Considerations (issued July 29, 2020)
N/A	FDA	Guidance for Industry and FDA Staff	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (issued June 27, 2025)
N/A	FDA	Guidance for Industry and FDA Staff	Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices (issued September 6, 2017)

The nonclinical verification and performance test results established that the subject device meets its design requirements and intended use, that the design differences with the predicate 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 Platform 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 Platform is substantially equivalent to its predicate device.