July 19, 2022

iRhythm Technologies, Inc.
Vishal Kanani
Senior Regulatory Affairs Program Lead
699 8th Street, Suite 600
San Francisco, California 94103

Re: K213409
Trade/Device Name: ZEUS System (Zio Watch)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DXH
Dated: July 15, 2022
Received: July 18, 2022

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,

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)*
K213409

Device Name
ZEUS System (Zio Watch)

Indications for Use *(Describe)*
The ZEUS System (Zio Watch), as part of the Zio Watch Service, is intended to process and analyze electrocardiogram (ECG) and photoplethysmogram (PPG) based data to detect and report on the presence of Atrial Fibrillation (AF) over the monitoring period. The report provides ECG information for the intended user to diagnose AF and contextual information for AF, both to be interpreted based on clinical judgment and experience. It is indicated for use on adult patients 22 years or older who are susceptible to developing or who have been diagnosed with AF. 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 K213409

I. General Information

Applicant:
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Date Prepared: October 15, 2021

II. Device Information

Trade Name:
ZEUS System (Zio Watch)

Generic/Common Name:
Programmable diagnostic computer

Classification Names:

- Programmable diagnostic computer [21CFR§870.1425]
- Telephone electrographic transmitter and receiver [21CFR§870.2920]

Regulatory Class:
Class II (Special controls)

Product Codes:

- DQK, Computer, Diagnostic, Programmable
- 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]
- **Secondary Predicate**: Verily Life Sciences, LLC. Study Watch with Irregular Pulse Monitor [K192415]

IV. Indications for Use

The Indications for Use statement for the subject ZEUS System (Zio Watch) is as follows:

The ZEUS System (Zio Watch), as part of the Zio Watch Service, is intended to process and analyze electrocardiogram (ECG) and photoplethysmogram (PPG) based data to detect and report on the presence of Atrial Fibrillation (AF) over the monitoring period. The report provides ECG information for the intended user to diagnose AF and contextual information for AF, both to be interpreted based on clinical judgment and experience. It is indicated for use on adult patients 22 years or older who are susceptible to developing or who have been diagnosed with AF. It is not intended for use on critical care patients.

V. Device Description

The Zio Watch Service, consisting of the Zio Watch (manufactured by Verily Life Sciences, LLC.; "Verily") and ZEUS System (Zio Watch) (developed by iRhythm Technologies, Inc.; "iRhythm"), is prescription based and intended to be used with non-critical care, ambulatory patients 22 years or older who have been diagnosed with or are susceptible to developing AF. The Zio Watch Service does not provide AF diagnosis. However, it is intended to provide the prescribing clinician with information such as ECG and AF Context, a visual display of AF presence in 30-minute intervals over a defined monitoring period from processing of PPG-based data, which is comparable to AF burden provided by the primary predicate ZEUS System. This information is intended to aid the clinician in their diagnosis, characterization, and/or management of AF per their clinical judgment and experience.

The ZEUS System (Zio Watch), the subject device of this 510(k) submission, is a software as a medical device (SaMD) system consisting of a collection of modules designed to process and analyze data from the Zio Watch into a curated report of preliminary findings intended for use by clinicians to aid in AF diagnosis.

The subject ZEUS System utilizes an artificial intelligence (AI) based ECG Analysis Software (ECGDL) to generate the initial ECG-based cardiac information provided to the clinician in Transmission Reports. In addition, continuously recorded PPG-based data is processed by a separate artificial intelligence (AI) based analysis software, the AF Context Engine (ACE), that detects the presence of AF. Specifically, the subject ZEUS System (Zio Watch) utilizes machine learning techniques for both the ECGDL and AF Context Engine algorithms.

These results are also presented along with the ECG data in the Zio Watch Transmission Reports. The reported cardiac information includes AF detection (including PPG-based AF summary) and heart rate measurements. The ECG-based preliminary findings in the Zio Watch Transmission Reports are quality reviewed by Certified Cardiographic Technicians (CCTs) prior to publishing. After CCT review, the report containing the preliminary findings and associated ECG are provided to clinicians via a secure website.

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

The subject ZEUS System (Zio Watch) 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 (Zio Watch) 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 (Zio Watch)**	**Primary Predicate Device: ZEUS System (K202527)**	**Secondary Predicate Device: Study Watch with Irregular Pulse Monitor (K192415)**
General Characteristics			
Manufacturer	iRhythm Technologies, Inc.	iRhythm Technologies, Inc.	Verily Life Sciences LLC
Classification	Class II	Same	Same
Product Code	**Classification Product Code**: DQK **Subsequent Product Codes**: DXH	**Classification Product Code**: DQK **Subsequent Product Codes**: DSI, DXH	**Classification Product Code**: DXH **Subsequent Product Codes**: DPS
Review Panel	Cardiovascular	Same	Same
Prescription/OTC	Prescription	Same	Same
Technology			
Data Input for AF Detection Algorithm	• ECG (Transmission) • PPG-based data (Continuous)	• ECG (Transmission) • ECG (Continuous)	PPG (to notify user in the event of irregular pulse and recommended acquisition of ECG)
AF Detection Algorithm	• AF Context Engine (ACE) • ECGDL	• AutoTrigger Engine (ATE) • ECGDL	Irregular Pulse Monitor
Beat Detection	• Present	Same	None
Interoperability	Zio Watch	• Zio XT Patch • Zio AT Patch • Zio Monitor	N/A

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 devices.

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. Algorithm Training and Validation

The subject ZEUS System (Zio Watch) utilizes machine learning techniques for both the ECGDL and AF Context Engine algorithms.

ECG Deep Learned (ECGDL) Algorithm

The ECG Deep Learned analysis algorithm (ECGDL) analyzes ECG recordings to provide beats, runs, rhythms, and heart rate detection.

AF Context Engine

AF Context Engine (ACE) is responsible for processing PPG-based data collected by the Zio Watch device to characterize the amount of AF over the patient's wear period. ACE retrieves PPG-based data in specific time segments (analysis intervals) from the Zio Watch and then provides AF presence/absence determination in intervals to be included in Zio Watch Transmission report.

Algorithm Training

The source of training data for the ECGDL and ACE algorithms of the subject device are continuous cardiac recordings from compatible cardiac monitors. Training data is collected from thousands of recordings, which have already undergone Certified Cardiographic Technician (CCT) review.

The ACE algorithm was trained using ECG data collected from Zio devices. In addition, the algorithm was tuned using PPG intervals recorded from devices similar to the Zio Watch.

The ECGDL algorithm was trained using ECG data collected from Zio devices for rhythm and beat detection.

Algorithm Validation

Verily Prospective Study (ACE):

The Verily Prospective Study data consists of multi-day PPG recordings obtained from the Zio Watch, along with ECG-based, CCT-reviewed reference rhythm labels obtained from reference Zio XT Patches worn simultaneously.

Recording device	Zio Watch
Channel(s)	Wrist-based PPG
Recording length	Up to 14 days
Environment	Ambulatory*

Demographics	Patients at least 22 years or older who are at risk of having an AF event, as determined by having a diagnosis of paroxysmal AF. **Age**: Median=67 [25%,75%] = [59,73] **Gender**: 45.5% Female **Regional Demographics (USA)**: Midwest: 8.0%, Mountain: 32.1%, West: 32.1%, Northeast: 14.3%, South: 13.4%

*In-clinic during enrollment

ZWAF Database (ECGDL):

The Zio Watch AF (ZWAF) database consists of ECG data obtained from Zio Watch as used in the Study Watch AF Detection At Home study ("Verily Prospective Study") sponsored by Verily Life Sciences LLC.

Recording device	Zio Watch
Channel(s)	Single-lead ECG: equivalent to lead I, on-wrist dry electrodes
Recording length	45 seconds
Environment	Ambulatory*
Demographics	Patients at least 22 years or older who are at risk of having an AF event, as determined by having a diagnosis of paroxysmal AF.

*In-clinic during enrollment

IX. Clinical Testing in Support of Substantial Equivalence Determination

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

X. 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 (Zio Watch) 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 (Zio Watch) is substantially equivalent to its predicate devices.