iRhythm Technologies, Inc.
Gabrielle Logan
Senior Regulatory Affairs Specialist
650 Townsend Street, Ste 500
San Francisco, California 94103

Re: K190593
Trade/Device Name: Zio® ECG Utilization Service (ZEUS) System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: July 19, 2019
Received: July 23, 2019

Dear Gabrielle Logan:

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,

Nicole Goodsell
Assistant Director (Acting)
External Heart Rhythm and Rate Devices Team
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190593

Device Name
Zio® ECG Utilization Service (ZEUS) System

Indications for Use *(Describe)*
The Zio ECG Utilization Service (ZEUS) System is intended to analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring. After patient monitoring by Zio XT or Zio AT Patch, a final report is generated based on the beat-to-beat information from the entire ECG recording. 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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Notification K190593

I. General Information

Applicant:
iRhythm Technologies, Inc.
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San Francisco, CA 94103, USA
Phone: 415-632-5700
Fax: 415-632-5701

Contact Person:
Gabrielle Logan
Sr. Regulatory Affairs Specialist
Phone: 415-214-7092
Email: glogan@irhythmtech.com

Date Prepared: August 22, 2019

II. Device Information

Trade Name:
Zio® ECG Utilization Service (ZEUS) System

Generic/Common Name:
Programmable diagnostic computer

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

Regulatory Class:
Class II

Product Codes:
DQK

III. Predicate Devices

The following predicate device has been selected:

- iRhythm Technologies, Inc. Zio® AT ECG Monitoring System [K181502]

No reference devices were used in this submission.

IV. Indications for Use

The Zio ECG Utilization Service (ZEUS) System is intended to analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring. After patient monitoring by Zio XT or Zio AT Patch, a final report is generated based on the beat-to-beat information from the entire ECG recording. 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 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.

V. Device Description

The ZEUS System is an electrocardiogram (ECG) processing and analysis system, designed to handle continuously recorded, single-lead ECG data. It downloads, stores, analyzes and aggregates the ECG data for a Certified Cardiographic Technician (CCT) to review and generate a report of the findings contained within the data; thereby enabling the provision of a complete ECG processing and analysis service.

Automated ECG analysis performance was quantified for any claimed analysis metrics. The resulting statistics demonstrate sensitivity and positive predictivity levels which satisfy requirements and minimize safety or efficacy concerns.

VI. Substantial Equivalence

The proposed indications for use statement for the Zio Utilization Service (ZEUS) System is substantially equivalent to the intended use in the cleared Indications for Use statement for the predicate device. The performance testing results demonstrate that the differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Therefore, the ZEUS System is determined to be substantially equivalent to the predicate device.

VII. Nonclinical Testing in Support of Substantial Equivalence Determination

There are no required FDA performance standards for the ZEUS System. Overall system performance testing was conducted as part of the verification activities on incremental changes to the ZEUS System to ensure performance as intended per specifications and to support a determination of substantial equivalence to the predicate device.

Nonclinical testing included:

- System performance testing
- Software verification testing

The results confirm by examination and provision of objective evidence that the design output met the design input requirements in conformance with the following list of recognized consensus standards:

Table 1: FDA-Recognized Consensus Standards & Guidance Document Summary

FDA#	Body	Number / Version	Title
5-70	AAMI ANSI ISO	14971:2007(R)2010 (Corrected 4 October 2017)	Medical Devices – Applications Of Risk Management To Medical Devices
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

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

VIII. Conclusion

The ZEUS System is substantially equivalent to the predicate device.