August 29, 2018

iRhythm Technologies, Inc.
Rich Laguna
Director of Quality and Regulatory Affairs
650 Townsend Street, Suite 500
San Francisco, California 94103

Re: K181502
Trade/Device Name: Zio AT ECG Monitoring System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH, DQK, DSI, DXH
Dated: June 5, 2018
Received: June 7, 2018

Dear Rich Laguna:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Arielle Drummond -S

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*

K181502

Device Name

Zio AT ECG Monitoring 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. While continuously recording patient ECG, both patient-triggered and automatically-detected arrhythmia events are transmitted to a monitoring center for reporting. After wear, 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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SECTION 5. 510(k) Summary

1. GENERAL INFORMATION

510(k) Sponsor

iRhythm Technologies, Inc.

650 Townsend Street, Suite 500

San Francisco, CA. 94103

Correspondence Person

Rich Laguna

Director of Quality and Regulatory Affairs

Contact Information

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Phone: (415) 632-5749

Date Prepared

08/29/2018

2. PROPOSED DEVICE

Proprietary Name

Zio® AT ECG Monitoring System

Common Name

Zio® AT ECG Monitoring System

Classification Name

Medical magnetic tape recorder [21 CFR§870.2800]

Programmable diagnostic computer [21CFR§870.1425]

Telephone electrocardiograph transmitter and receiver [21CFR§870.2920]

Arrhythmia detector and alarm (including ST-segment measurement and alarm) [21 CFR§870.1025]

Regulatory Class

Class II

Product Codes

DSH, Recorder, Magnetic Tape, Medical

DQK, Computer, Diagnostic, Programmable

DXH, Transmitters And Receivers, Electrocardiograph, Telephone

DSI, Detector And Alarm, Arrhythmia

3. PREDICATE DEVICE (ORIGINALLY CLEARED DEVICE)

iRhythm Technologies, Inc. Zio AT ECG Monitoring System (K163512)

4. DEVICE DESCRIPTION

The ZEUS System was most recently 510(k) cleared under K163512 as part of the Zio AT ECG Monitoring System ("Zio® AT"). The original cleared ECG monitoring system components consisted of the 1) Zio AT Patch Recorder Device 2) Zio AT Wireless Gateway Device with Bluetooth and Cellular Technology, and 3) ZEUS System for analysis and reporting. This submission discusses the changes made to the ZEUS System only. The ZEUS System is an electrocardiogram (ECG) analysis and reporting software system, designed to process continuously recorded, signal-lead ECG data. The ZEUS System downloads, stores, analyzes and sorts the ECG data to allow iRhythm's Certified Cardiographic Technicians (CCTs) to generate and distribute a report of the findings contained within the data, thereby enabling the provision of a complete ECG processing and analysis service.

The ZEUS System is considered modified as a result of updating its rhythm classification algorithm from a rule and machine-learning implementation to a deep-learning basis. The comparison to the originally cleared device and performance test results demonstrate that the modified ZEUS System is substantially equivalent to the original ZEUS System cleared under K163512, and that the intended use of the device can be consistently fulfilled as originally cleared.

5. INDICATIONS FOR USE

The device is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring. While continuously recording patient ECG, both patient-triggered and automatically-detected arrhythmia events are transmitted to a monitoring center for reporting. After wear, 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.

6. SUBSTANTIAL EQUIVALENCE SUMMARY

The indications for use statement for the modified ZEUS System is an identical reflection of the indications for use as represented in the originally cleared device. The performance testing results demonstrate that the differences in the technological characteristics between the devices do not raise new issues of safety or effectiveness. Therefore, the modified ZEUS System is determined to be substantially equivalent to the original ZEUS System device. A comparison table outlining the differences and similarities between the modified and original ZEUS System is provided in *Table 5.1*.

Table 5.1: Substantial Equivalence Summary Table

Feature/ Function	**Original Device:** Zio AT ECG Monitoring System (K163512)	**Modified Device:** ZEUS System
General Characteristics		
Classification	Class II	Class II
Classification Regulation(s)	21 CFR 870.2800 21 CFR 870.1425 21 CFR 870.2920 21 CFR 870.1025	21 CFR 870.2800 21 CFR 870.1425 21 CFR 870.2920 21 CFR 870.1025
Product Code	DSH, DQK, DXH, DSI	DSH, DQK, DXH, DSI
Patient Environment	Ambulatory	Ambulatory
Patient Population	Non-pediatric, non-critical care patients	Non-pediatric, non-critical care patients
Technological Characteristics		
Data Input	Digital long-term continuous and transmission ECG	Digital long-term continuous and transmission ECG
Data Download	Yes	Yes
Data Storage	Yes	Yes
ECG Analysis	Beat Runs Rhythm Types Heart Rates	Beat Runs Rhythm Types Heart Rates
Rhythm Detection Algorithm	ECGML	ECGML and ECGDL

Feature/ Function	**Original Device:** Zio AT ECG Monitoring System (K163512)	**Modified Device:** ZEUS System
Rhythm Types	- Atrial fibrillation - Complete heart block - Second degree AV block-type II - Pause >3 seconds - Sinus rhythm - Supraventricular tachycardia - Ventricular bigeminy - Ventricular fibrillation - Ventricular tachycardia - Ventricular trigeminy	- Atrial fibrillation - Complete heart block - Second degree AV block-type II - Pause >3 seconds - Sinus rhythm - Supraventricular tachycardia - Ventricular bigeminy - Ventricular fibrillation - Ventricular tachycardia - Ventricular trigeminy - Second degree AV block-type I - Ectopic atrial rhythm - Junctional rhythm - Idioventricular rhythm
Result Integrator	Algorithm Controller	Algorithm Controller, updated to initiate ECG Analysis through ECGDL, and integrate the ECGML and ECGDL labels
Architecture	Integrated Analysis Tool	Integrated Analysis Tool
Platform	PC / Server Mix to Clinician & Patient Websites	PC / Server Mix to Clinician & Patient Websites
QA Tool	Yes	Yes, updated to support the expanded rhythms
Report Output	Yes	Yes
ZEUS Web Services	Store and retrieve the integrated ECGML Labels to ZEUS Database	Store and retrieve the integrated ECGML and ECGDL Labels to ZEUS Database

7. PERFORMANCE DATA

Safety and performance of the modified ZEUS System has been evaluated and verified in accordance with design specifications and applicable performance standards. The modified device's arrhythmia algorithm detection was tested in accordance to *AAMI ANSI EC57: 2012, Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms*; it was also evaluated according to *60601-2-47:2012*, *Medical Electrical Equipment- Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems*. Additionally, the information presented in this submission has been developed in consideration of the recommendations contained in FDA Guidance documents, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and *"Content of Premarket Submission for Management of Cybersecurity in Medical Devices"*.

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

8. CONCLUSION

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing comparison to the originally cleared device, the modified ZEUS System raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device.