DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 21, 2014

Irhythm Technologies, Inc.
Rich Laguna
Director Qa/ra
650 Townsend Street, Suite 380
San Francisco, California 94103

Re: K142681
Trade/Device Name: Zeus (zio Ecg Utilization Service) System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: October 22, 2014
Received: October 24, 2014

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K142681**

Device Name: ZEUS (ZIO ECG Utilization Services) System

Indications for Use:

The ZEUS System is intended for use by qualified medical professionals for the assessment ambulatory electrocardiogram (ECG) data from adult patients 18 years or older. The system is intended to be marketed as a service that downloads and analyzes up to 14 days of ECG data. Analysis metrics are provided in a report which is available for clinician review and printing. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.

Prescription Use **X**	And/Or	Over the Counter Use ____
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 5
510(k) SUMMARY

This summary of the 510(k) premarket notification for the ZEUS System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

SECTION 5
510(k) SUMMARY (Cont.)

510(k) Notification K142681

GENERAL INFORMATION

Applicant:
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San Francisco, CA 94103
U.S.A
Phone: 415-632-5700
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Contact Person:
Rich Laguna
Director Quality & Regulatory Affairs
eMail: rlaguna@irhythmtech.com
Phone: 415-632-5749
Fax: 415-632-5701

Date Prepared: October 22, 2014

DEVICE INFORMATION

Classification:
Computer, diagnostic, programmable, 21 CFR§870.1425

Product Code:
DQK

Trade Name:
ZEUS (ZIO ECG Utilization Services) System

Generic/Common Name:
Programmable diagnostic computer

PREDICATE DEVICE(S)
ZEUS (ZIO ECG Utilization Services) System (K091075)

INDICATIONS FOR USE
The ZEUS System is intended for use by qualified medical professionals for the assessment ambulatory electrocardiogram (ECG) data from adult patients 18 years or older. The system is intended to be marketed as a service that downloads and analyzes up to 14 days of ECG data. Analysis metrics are provided in a report which is available for clinician review and printing. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.

PRODUCT DESCRIPTION
The ZIO ECG Utilization Service System ("ZEUS System") is an electrocardiogram (ECG) processing and analysis system, designed to handle continuously recorded, single-lead ECG data. Once the ECG data is downloaded, the data is processed through the algorithm and delivered to the QA Tool module where the results are reviewed and/or adjusted by iRhythm Certified Cardiographic Technicians (CCT's) for accuracy. iRhythm trained Patch in-take and CCT personnel follow internal procedures for processing and are made aware of the algorithm performance anomalies. Any software anomalies are visible to and manually corrected by iRhythm Technologies CCT's during the QA review and/or Patch Report edits. The CCT generates a final report of the ECG findings contained within the data; thereby enabling the provision of a complete ECG processing and analysis service.

The ZEUS System is substantially equivalent to the previously 510(k) cleared (K091075) with the same intended use.

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.

SECTION 5
510(k) SUMMARY (Cont.)

SUBSTANTIAL EQUIVALENCE

The indications for use for the ZEUS System are equivalent to the indications for use for the predicate device. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the ZEUS System is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

There are no required FDA performance standards for the product code DQK of the ZEUS System. All necessary software verification and validation was conducted on the modified ZEUS System to support determination of substantial equivalence to the predicate devices. The results confirm by examination and provision of objective evidence that the software design output met the software design input requirements in conformance with the following list of recognized standards:

- AAMI / ANSI / ISO ISO 14971:2007 Medical Devices-Application of Risk Management to Medical Devices / Use & Design Risk analysis
- AAMI / ANSI / ISO 60601-2-47:2012, medical electrical equipment -- part 2-47: particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems. (Cardiovascular)

SUMMARY

The ZEUS (ZIO ECG Utilization Services) System is substantially equivalent to the predicate device.