



March 7, 2019

Biofourmis Singapore Pte. Ltd.
% Michael Daniel
President
Daniel & Daniel Consulting, LLC
340 Jones Lane
Gardnerville, Nevada 89460

Re: K182344
Trade/Device Name: RhythmAnalytics
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: February 1, 2019
Received: February 5, 2019

Dear Michael Daniel:

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,


Jessica E. Paulsen -S

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K182344

Device Name

RhythmAnalytics

Indications for Use (Describe)

RhythmAnalytics is a software application for the assessment of cardiac arrhythmias using single-lead ECG data in subjects over 18 years of age. It is intended for use by a healthcare solution integrator to build web or mobile applications to let qualified healthcare professionals review and confirm the analytic result. The product supports downloading and analysing data recorded in compatible formats from any FDA cleared device used for the arrhythmia diagnostics such as Holter, event recorder, or other similar devices when assessment of the rhythm is necessary. RhythmAnalytics can also be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems, such as an ECG management system. RhythmAnalytics provides ECG signal processing and analysis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis. RhythmAnalytics is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.

The product can be integrated into medical devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device.

RhythmAnalytics interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

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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Premarket Notification 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K182344

Applicant Information:

Date Prepared: March 01, 2019
Name: Biofourmis Singapore Pte.Ltd.
Address: Vision Exchange, #07-15
2 Venture Drive
Singapore 608526

Contact Person: Michael A Daniel, Consultant
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Office Number: (775) 392-2970
Facsimile Number: (610) 545-0799

Device Information:

Trade Name: RhythmAnalytics
Common Names: ECG Analysis System
Classification Name(s): Programmable Diagnostic Computer/Electrograph
Product Code/ Regulation: DQK, 21 CFR 870.1425
DPS, 21 CFR 870.2340
Classification: Class II

Predicate Device:

- CardioLogs ECG Analysis Platform – K170568

Device Description:

RhythmAnalytics consists of (1) A web application programming interface (API) which an authentic user to upload single-lead ECG data and reports ECG interpretation results, and (2) An automated proprietary algorithm, i.e., cardiac beats/arrhythmias detection which measures and analyzes ECG data to provide qualified healthcare professional supportive information for review.

RhythmAnalytics is only intended to analyze recordings performed on adults (over the age of 18). RhythmAnalytics works in the following sequence:

- Accept uploading digital ECG files via secure API;
- Analyse the uploaded ECG using RhythmAnalytics proprietary algorithm, which detects cardiac beats/arrhythmias and intervals including:
 - Heart rate determination
 - RR Interval measurements

- QRS
- Non-paced arrhythmias
- Non-paced ventricular arrhythmia calls
- Ventricular ectopic beats
- RhythmAnalytics returns the interpretation result to be reviewed by a qualified healthcare professional.

Indications for Use:

RhythmAnalytics is a software application for the assessment of cardiac arrhythmias using single-lead ECG data in subjects over 18 years of age. It is intended for use by a healthcare solution integrator to build web or mobile applications to let qualified healthcare professionals review and confirm the analytic result. The product supports downloading and analysing data recorded in compatible formats from any FDA cleared device used for the arrhythmia diagnostics such as Holter, event recorder, or other similar devices when assessment of the rhythm is necessary. RhythmAnalytics can also be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems, such as an ECG management system. RhythmAnalytics provides ECG signal processing and analysis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis. RhythmAnalytics is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.

The product can be integrated into medical devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device.

RhythmAnalytics interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

Summary Comparison to Predicate:

The following tables provide a summary of substantial equivalence between the subject device and the cited predicate. The subject device has the same intended use and substantially equivalent characteristics that do not raise different questions of safety or effectiveness.

Comparison to Predicate Device:

The following table provides a comparison of the detection features and device comparison of RhythmAnalytics and the predicate device:

Detection Features comparison:

Detection Feature	RhythmAnalytics	CardioLogs ECG Analysis Platform
Heart rate determination for non-paced adult	Yes	Yes
QRS Detection	Yes	Yes
Non-paced arrhythmia interpretation for adult patients	Yes	Yes
Non-paced ventricular arrhythmia calls	Yes	Yes
Intervals measurements	Yes	Yes
Ventricular ectopic beat detection	Yes	Yes
Patient Population	Adult	Adult

Device comparison:

	Subject device	Predicate Device	Comparison to predicate device
Device Name	RhythmAnalytics	CardioLogs ECG Analysis Platform	N/A
Manufacturer	Biofourmis Singapore Pte.Ltd.	CardioLogs Technologies	N/A
510(k) #	K182344	K170568	N/A
Regulation Number	21 CFR 870.1425 21 CFR 870.2340	21 CFR 870.1425 21 CFR 870.2340	Same
Class	II	II	Same
Device Class/Name	Electrocardiograph	Electrocardiograph	Same

	Subject device	Predicate Device	Comparison to predicate device
Product Code	DPS, DQK	DPS, DQK	Same
Level of Concern	Major	Moderate	Different

	Subject device	Predicate Device	Comparison to predicate device	Safety Impact	Effectiveness impact
Indication for Use	Refer to Section "Indications for Use"	Refer to K170568, Section 7.2	Both devices are intended for the same use.	No impact. Same for indication for use.	No impact. Same for indication for use.
Fundamental scientific technology	RhythmAnalytics consists of:	CardioLogs ECG Analysis Platform consists of:	RhythmAnalytics and the predicate device both consists of:		
	1. A web application programming interface (API) which allows uploading of ECG data and generate ECG interpretation results.	1. An interface which provides tools to measure, analyses and review numerous ECGs coded in java language under the Angular and D3.js frameworks;	1. A cloud-based API that works the same way.	No impact. Both provide similar interface but coded in difference programming language which should not cause any safety impact to patient.	No impact. Both provide similar interface but coded in difference programming language which should not cause any effectiveness impact.
	2. An automated proprietary algorithm, i.e., cardiac beats/arrhythmias detection which measures and analyses ECG data to provide qualified healthcare professional supportive information for review.	2. An automated proprietary ECG interpretation support algorithm which measures and analyses ECGs to provide supportive information for ECG diagnosis, written in Python language.	2. Automated proprietary algorithm to detect cardiac arrhythmias, heart rate and interval measurements.	No impact. Both provided arrhythmia interpretation are not intended to be the sole means of diagnosis. The interpretations are offered to physicians and clinicians on an advisory or assistive basis.	No impact. The difference in programming language shouldn't make any effect on algorithms.
	Any healthcare solution integrator	This application can be accessed	RhythmAnalytics therefore does not		

	Subject device	Predicate Device	Comparison to predicate device	Safety Impact	Effectiveness impact
	leveraging on our RhythmAnalytics API can build web or mobile application to let qualified healthcare professional review and confirmation the analytic result.	through an Internet connection and a web browser or is directly connected to the CardioLogs' API.	present any major technological innovations compared to the predicate device.		

Summary of Performance Testing

Tests have been performed in compliance with the appropriate recognized consensus standards. Testing described in this 510(k) consisted of verification of all design input requirements and product specifications. Performance testing included the evaluation of sensitivity, specificity, and positive and negative predictive values. All clinical input requirements were validated against a gold standard. No residual anomalies appeared during verification and software validation tests. General usability tests, analyzing the users' ability to login, upload, review and download were performed and met all requirements. All software validation testing was completed successfully and met all requirements.

Software

Biofourmis followed IEC 62304:2015 and the FDA Guidance Document, "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (January, 2002) with respect to software development and validation. The Biofourmis software is classified as a "major level of concern" per the FDA guidance document.

Verification and validation testing was completed in compliance with the following standards and guidance documents:

- AAMI ANSI IEC 62304:2015, Medical device software – Software life cycle processes
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (January, 2002)
- AAMI/ANSI EC57:2012 - Testing and Reporting Performance Results of Cardiac Rhythm And ST-Segment Measurement Algorithms
- IEC 62366-1 Edition 1.0 2015-02 - Medical devices - Application of usability engineering to medical devices

Conclusion

Based upon the intended use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, RhythmAnalytics has been shown to be substantially equivalent to the legally-marketed predicate.