



November 7, 2017

Rooti Labs Ltd.
Ms. Sue Chuang
Chief Operating Officer
5f-1, No.17, Zhouzi St., Neihu Dist.
Taipei, 11493 TW

Re: K163694

Trade/Device Name: Rooti Rx System ECG Event Recorder, Rooti Link APP Software
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: December 9, 2016
Received: December 28, 2016

Dear Ms. Sue Chuang:

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 (DICE) 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 (DICE) 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style. A large, light blue "FDA" watermark is visible in the background behind the signature.

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)
K163694

Device Name

Rooti Rx System ECG Event Recorder, Rooti Link APP Software

Indications for Use (Describe)

- The intended use of the Rooti Rx System is to allow a patient at home or in the workplace to record single-lead electrocardiography (ECG) data for post-analysis by medical professionals. The Rooti Rx device stores the ECG data, and the recorded data is transmitted to a medical professional's iOS device via Wi-Fi at a later time.
- The device is not intended to be used on critical care patients. The Rooti Rx System is indicated for use on general care patients and on patients who are 21 years of age or older.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

1. Company Identification

Rooti Labs Ltd.

5F-1, No.71, Zhouzi St., Neihu Dist., Taipei, Taiwan

Tel: +886-2-2656-0618

2. Submitter's Name and Address

Sue Chuang

Email: sue.chuang@rootilabs.com

Tel: +886-2-2656-0618

3. Device Trade Name: Rooti Rx System ECG Event Recorder, Rooti Link APP Software

Product name: Rooti Rx System

Model/Type name: Rooti Rx System ECG Event Recorder

Regulation Number: 21 CFR 870.2910

Product Code: DRG

Device Class: II

4. Predicate Device

Zephyr Technology, BIOMODULE 3-M1, 510(k) number K123658.

5. Intended Use

- The intended use of the Rooti Rx System is to allow a patient at home or in the workplace to record single-lead electrocardiography (ECG) data for post-analysis by medical professionals. The Rooti Rx device stores the ECG data, and the recorded

data is transmitted to a medical professional's iOS device via Wi-Fi at a later time.

- The device is not intended to be used on critical care patients. The Rooti Rx System is indicated for use on general care patients and on patients who are 21 years of age or older.

6. Device Description

Rooti Rx System is a wearable single lead ECG recording device, composed by Rooti Rx, patch, charging dock and Rooti Link. When operating Rooti Rx System, medical professionals should use disposable, off the shelf, standard ECG electrodes which are not claimed in the system.

7. Compliance of Recognized Consensus Standard

USA Standard				
NO.	Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title of Standard
1	2-156	AAMI ANSI ISO	10993-1:2009/(R)2013	Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
2	19-6	IEC	60601-1-11 Edition 1.0 2010-04	Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment [Including: Technical Corrigendum 1 (2011)]
3	19-4	AAMI ANSI	ES60601-1:2005/(R)2012 And A1:2012,	C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
4	19-2	AAMI ANSI IEC	60601-1-2:2007/(R)2012	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility Requirements And Tests (Edition 3)
5	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

8. Safety and Effectiveness Substantial Equivalence Comparison

Device Name	BIOMODULE 3-M1	Rooti Rx System	Comparison
Applicant	Zephyr Technology	Rooti Labs Limited	-
510(K) Number	K123658		-
Regulation Number	870.2360	870.2910	
Classification	Class II	Class II	
Product Code	DRX	DRG	-
Intended Use	<p>The intended use of the BioModule 3-M1 is to provide a General Ward Monitoring facility for detecting, storing and transmitting physiological data to a qualified receiving station. The scientific concept on which this device is based on the principle that low level electrical pulses from the heart are measurable of the surface of the skin. This device functions by capturing these electrical pulses via electrodes and delivering these signals to sophisticated electronics for processing. The calibration is established by the factory and yields accurate and calibrated signals that can maintain calibration over its useful life.</p>	<p>- The intended use of the Rooti Rx System is to allow a patient at home or in the workplace to record single-lead electrocardiography (ECG) data for post-analysis by medical professionals. The Rooti Rx device stores the ECG data, and the recorded data is transmitted to a medical professional's iOS device via Wi-Fi at a later time.</p> <p>- The device is not intended to be used on critical care patients. The Rooti Rx System is indicated for use on general care patients and on patients who are 21 years of age or older.</p>	Similar
Indication For Use	<p>The BioModule 3-M1 is a physiological monitoring telemetry device intended for monitoring ambulatory patients in alternate care settings. The device consists of adhesive electrodes and an electronics module. The device stores and transmits vital sign data including ECG, heart rate, respiration rate, body orientation and activity. The BioModule 3-M2 provides a facility to detect and transmit single lead ECG signals to be received by qualified instruments.</p> <p>The BioModule 3-M1 collects and transmits measurements captured in alternate care settings as prescribed by the health care professional. Breathing rate values are accurately transmitted only during sedentary periods.</p> <p>The BioModule 3-M1 is indicated for</p>	<p>- The intended use of the Rooti Rx System is to allow a patient at home or in the workplace to record single-lead electrocardiography (ECG) data for post-analysis by medical professionals. The Rooti Rx device stores the ECG data, and the recorded data is transmitted to a medical professional's iOS device via Wi-Fi at a later time.</p> <p>- The device is not intended to be used on critical care patients. The Rooti Rx System is indicated for use on general care patients and on patients who are 21 years of age or older.</p>	Similar

	use as a general patient monitor to provide physiological information as part of general ward monitoring system.		
Data Storage Capacity	140 hrs	7 days	Rooti Rx System has more capacity
Method Of Application	Off the shelf adhesive electrode	Off the shelf adhesive electrode	Same
Number of ECG	1	1	Same
ECG resolution	12	24	Rooti Rx
ECG sampling rate (Hz)	1000	500	Both are more than double the highest useful frequency component (40Hz).
Water resistant	Yes	Yes	Same
Data transmission	wireless	wireless	Same
Power source	Rechargeable battery	Rechargeable battery	Same
Weight (g)	33	14	Rooti Rx System is lighter
Dimensions (mm)	88 x 48 x 8	62x22.5x8.45	Rooti Rx System is smaller

9. Conclusion

Rooti Rx System is a wearable single lead ECG recording device, composed by Rooti Rx, Patch, Charging dock and Rooti Link. The intended use of the Rooti Rx System is

to allow a patient at home or in the workplace to record single-lead electrocardiography (ECG) data for post-analysis by medical professionals. The Rooti Rx device stores the ECG data, and the recorded data is transmitted to a medical professional's iOS device via Wi-Fi at a later time.

According to the substantial equivalence discussion, the Rooti Rx System is substantially equivalent to the predicate devices in all respects. The intended use and the indication for use for the Rooti Rx System are substantially equivalent to the intended use and the indication for use for the predicate device. The performance testing results demonstrate that any differences in the technological characteristics between the devices are incidental and not significant which do not raise any new issues of safety or efficacy. Therefore, the Rooti Rx System is substantially equivalent to the predicate device