June 23, 2022

Sigknow Biomedical Co.,Ltd.
Hsiao-Fan Liu
Regulatory Affairs
6F., No. 760, Sec. 4, Bade Rd., Songshan Dist,
Taipei City, 105412
Taiwan

Re: K213233
Trade/Device Name: EZYPRO ECG Recorder (Model: UG02)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Code: DRG
Dated: May 16, 2022
Received: May 26, 2022

Dear Hsiao-Fan Liu:

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,

Jennifer Shih
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213233

Device Name
EZYPRO ECG Recorder (Model: UG02)

Indications for Use *(Describe)*
EZYPRO ECG Recorder (Model: UG02) is a prescription-only, single-patient-use, continuously recording single-lead cardiac rhythm recorder that can be worn up to 14 days each time through recharge. It is indicated for use on patients who are older than 21 years old. At the end of the recording, the recorded ECG data can be transferred in an available file on PC via the USB connection.
During wearing, EZYPRO ECG Recorder (Model: UG02) can digitally transmit ECG data to the mobile device with the APP (EZY iSee) embedded through Bluetooth technology, supporting spot checks on signals. EZY iSee does not contain diagnostic interpretation.
UG02 setting tool is a program executed on the Windows OS platform and to provide an interface for setting up operational parameters of EZYPRO ECG Recorder (Model: UG02) and downloading the recorded ECG data.

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.

510(k) SUMMARY

5.1 Type of Submission Traditional

5.2 Date of Summary 06/17/2022

5.3 Submitter Sigknow Biomedical Co., Ltd.

Address: 6F., No.760, Sec. 4, Bade Rd., Songshan Dist., Taipei City 105, Taiwan (R.O.C.)

Phone: +886-2-2761-2577

Contact: Hsiao-Fan Liu
vera.liu@sigknow.com.tw

5.4 Identification of the Device

Proprietary/Trade Name:	EZYPRO ECG Recorder (Model: UG02)
Model Number:	UG02
Regulation Description:	Radiofrequency physiological signal transmitter and receiver.
Review Panel:	Cardiovascular
Regulation Number:	870.2910
Product Code:	DRG
Device Class:	II

5.5 Identification of the Predicate Device

Predicate Device Name:	Rooti Rx System ECG Event Recorder, Rooti Link APP Software
Model Number:	—
510(k) Number:	K163694
Manufacturer:	Rooti Labs Ltd.
Regulation Number:	870.2910
Product Code:	DRG
Device Class:	II

5.6 Identification of the Reference Device

Reference Device Name:	ZIO ® Patch
Model Number:	—
510(k) Number:	K121319
Manufacturer:	iRhythm Technologies, Inc.
Regulation Number:	870.2800
Product Code:	DSH
Device Class:	II

5.7 Intended Use/Indications for Use of the Device

EZYPRO ECG Recorder (Model: UG02) is a prescription-only, single-patient-use, continuously recording single-lead cardiac rhythm recorder that can be worn up to 14 days each time through recharge. It is indicated for use on patients who are older than 21 years old. At the end of the recording, the recorded ECG data can be transferred in an available file on PC via the USB connection.

During wearing, EZYPRO ECG recorder (model: UG02) can digitally transmit ECG data to the mobile device with the APP (EZY iSee) embedded through Bluetooth technology, supporting spot checks on signals. EZY iSee does not contain diagnostic interpretation.

UG02 setting tool is a program executed on the Windows OS platform and to provide an interface for setting up operational parameters of EZYPRO ECG Recorder (Model: UG02) and downloading the recorded ECG data.

5.8 Device Description

EZYPRO ECG Recorder (Model: UG02) can record cardiac rhythm up to 14 days. Wearing duration is adjustable based on different needs of the physicians.

The recorder is lightweight, wire free, and easy to carry around; Will not interfere patient's daily routine or any activities.

Patient’s symptomatic episodes can be marked by proactive pressing the blue button on the recorder; Physicians could later look back at the data and use it in the diagnosis.

EZYPRO ECG Recorder is solely intended for manual interpretation of the recorded ECG and heart rate detection using the integrated software. The ECG signal recorded by this device is not intended for automated analysis.

5.9 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, EZYPRO ECG Recorder (Model: UG02).

- Reliability Test
  - Reliability Test (ME)
  - Reliability Evaluation (500 cycles reusable)
- Shelf Life Test
- Biocompatibility
  - Biological evaluation of medical device
  - In Vitro Cytotoxicity Test (Agar Diffusion)
  - Intracutaneous Irritation Study in Rabbits
  - Skin Sensitization Study in Guinea Pigs (Maximization Test)
- Software
  - Recorder - Firmware Validation
  - EZY iSee - Software Validation
  - UG02 Setting Tool - Software Validation
  - Cybersecurity - Cybersecurity Management
- Electromagnetic compatibility and electrical safety test
  - IEC 60601-1 Test
  - EMC Test
  - Radio Spectrum Test
  - SAR Evaluation
  - Safety Requirements for Portable Sealed Secondary Cells
  - Lithium Polymer Battery Safety Test
  - IEC 60601-1-11 Test
  - Energy Reduction Test
- Performance test

  - IEC 60601-2-47 Test
  - Product Function Test (EE)
  - Disposable ECG electrodes Test
  - QRS and Heart Rate Accuracy
- HFE/UE
- MR Unsafe Evaluation
- RF Wireless Evaluation

All the test results demonstrate EZYPRO ECG Recorder (Model: UG02) meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

5.10 <u>Clinical Testing</u>

No clinical test data was used to support the decision of substantial equivalence.

5.11 Substantial Equivalence Determination

EZYPRO ECG Recorder (Model: UG02) submitted in this 510(k) file is substantially equivalent in intended use, safety and performance to the cleared Rooti Rx System (K163694). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject device	Predicate device	Substantial equivalence determination
510(k) No.	K213233	K163694	N/A
Proprietary Name	EZYPRO ECG Recorder (Model: UG02)	Rooti Rx System ECG Event Recorder, Rooti Link APP Software	N/A
Manufacturer	Sigknow Biomedical Co., Ltd.	Rooti Labs Limited	N/A
Regulation Number	21 CFR 870.2910	21 CFR 870.2910	***Same***
Classification	Class II	Class II	***Same***
Product Code	DRG	DRG	***Same***
Intended Use	EZYPRO ECG Recorder (Model: UG02) is a prescription-only, single-patient-use, continuously recording single-lead cardiac rhythm recorder that can be worn up to 14 days each time through recharge. It is	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	***Similar*** The subject device is to record single-lead cardiac rhythm from patients who are older than 21 years old; its medical indication is

Item	Subject device	Predicate device	Substantial equivalence determination
	indicated for use on patients who are older than 21 years old. At the end of the recording, the recorded ECG data can be transferred in an available file on PC via the USB connection. During wearing, EZYPRO ECG recorder (model: UG02) can digitally transmit ECG data to the mobile device with the APP (EZY iSee) embedded through Bluetooth technology, supporting spot checks on signals. EZY iSee does not contain diagnostic interpretation. UG02 setting tool is a program executed on the Windows OS platform and to provide an interface for setting up operational parameters of EZYPRO ECG Recorder (Model: UG02) and downloading the recorded ECG data.	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.	same as the predicate device. The recorded data could be transmitted wireless to a medical professional's equipment. The subject device has additional component, UG02 setting tool that can set up the operational parameters and download the data.

Item	Subject device	Predicate device	Substantial equivalence determination
Data Storage Capacity	14 days	7 days	***Different*** The subject device has more capacity. And the software validation and performance tests could demonstrate that it would not affect the safety and effectiveness.
Method of Application	Designed adhesive electrode	Off the shelf adhesive electrode	***Different*** The subject device has exclusive electrode, and the function of exclusive electrode has been tested. It could demonstrate the substantial equivalence of devices.
ECG channel	Channel 1, Single lead	Channel 1, Single lead	***Same***
Electrode Position	Left Sternum, inclined (Self-defined position called "ECG Channel A")	Left Sternum, horizontal	***Different*** A reference device (ZIO Patch, K121319) which are applied to the similar position as the subject device was used to support the

Item	Subject device	Predicate device	Substantial equivalence determination
			technological characteristic. The relevant evaluation and tests could demonstrate the subject device is substantially equivalent to the predicate.
ECG resolution	18 bits, ±5mV	24 bits, 6mVp-v, offset ±300mV	***Different*** The subject device has lower ECG resolution. Performance tests shown that it meets the requirements and the device is substantially equivalent to the predicate.
ECG sampling rate (Hz)	256	500	***Different*** Both are more than double the highest useful frequency component (40Hz). Performance tests shown that it meets the requirements and the

Item	Subject device	Predicate device	Substantial equivalence determination
			device is substantially equivalent to the predicate.
Water resistant	Yes	Yes	***Same***
Data transmission	Bluetooth	Wifi	***Different*** Although they are different in data transmission, it doesn't affect the device function. Software validation demonstrated that it meets the requirements.
Power source	360 mAh lithium battery (Rechargeable battery)	240 mAh lithium battery (Rechargeable battery)	***Similar*** The subject device has more quantity of electricity. The relevant electric safety tests shown that it meets the requirements.
Weight (g)	20	14	***Similar*** Although the subject device is heavier due to the battery, it

Item	Subject device	Predicate device	Substantial equivalence determination
			doesn't affect the device function.
Dimensions (mm)	47 (L) x 32 (W) x 12 (H) mm	62 x 22.5 x 8.45 mm	***Similar*** Although the subject device is larger due to the battery, it doesn't affect the device function.

5.12 Similarity and Difference

In terms of the intended use, the subject device and the predicate device are much similar.

The subject device can be worn up to 14 days to record ECG data. During wearing, it can digitally transmit ECG data to the mobile device with the APP (EZY iSee) embedded through Bluetooth technology, supporting spot checks on signals just for making sure the device are working normally. At the end of the recording, the recorded ECG data can be downloaded from recorder for post-analysis by medical professionals.

The predicate device can be worn up to 7 days to record ECG data. During wearing, the recorded data is transmitted to a medical professional's iOS device via Wi-Fi at a later time for post-analysis.

Both of them are used on general care patients and on patients who are 21 years of age or older. They are both used at home or in the workplace, and the recorded data is finally received to medical professionals.

Therefore, the intended use and the indication for use for the subject device are substantially equivalent to the predicate device.

In the terms of electrode position, the subject device adopts a specific position named "ECG Channel A", which is different from the predicate. Therefore, a reference device (ZIO Patch, K121319) applied to a similar position was added to support the technological characteristic.

In terms of the specification, because of the larger battery, the subject device has bigger data storage capacity, power source, weight and dimension so that it can record ECG data up to 14 days.

On the other hand, although there are some differences on data transmission technology, ECG resolution, and ECG sampling rate, they do not affect the safety and performance of the subject device based on the provided test reports.

In terms of the ECG patch, the subject device has exclusive electrode, and the function of exclusive electrode has been tested to demonstrate substantial equivalence

5.13 Conclusion

In conclusion, according to the substantial equivalence discussion, the EZYPRO ECG Recorder (Model: UG02) is substantially equivalent to the predicate device in all respects. The intended use for the EZYPRO ECG Recorder (Model: UG02) are substantially equivalent to 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 as compared to the predicate. Therefore, the EZYPRO ECG Recorder (Model: UG02) is substantially equivalent to the predicate device.