February 3, 2025

iHealth Labs, Inc.
Tianyang Liu
Director of Medical Devices
880 W Maude Ave
Sunnyvale, California 94085

Re: K243146
Trade/Device Name: iCare APP
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DXN, OCH, PUH, OUG
Dated: September 30, 2024
Received: September 30, 2024

Dear Tianyang 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
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

Enclosure

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)*
K243146

Device Name
iCare App

Indications for Use *(Describe)*

The iCare App is intended for use in the home and clinical settings as an aid for users and their healthcare professionals to view test results which are measured by iHealth devices to better manage user's health and get feedback from their professional care team.

The iCare App can also connect to medical devices and/or non-medical devices and get data from devices during measurement or from the data stored in memory of the device for enhanced data managements. Data can be transmitted, displayed, and stored in the App.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. Submitter Information

Name: iHealth Labs, Inc.

Address: 880 W Maude Ave, Sunnyvale, CA 94085

Phone Number: 1-855-816-7705

Contact: Tianyang Liu

Date of Preparation: September 30, 2024

2. Device Information

Trade name: iCare APP

3. Classification

Product Code and Regulation Number:

MWI: Sec. 870.2300 Cardiac monitor (including cardiotachometer and rate alarm).

DXN: Sec. 870.1130 Noninvasive blood pressure measurement system.

OCH: Sec. 870.2700 Oximeter.

PUH: Sec. 870.2770 Impedance plethysmograph.

OUG: Sec. 880.6310 Medical device data system

Class Classification: II

Panel: 870 Cardiovascular

4. Predicate Device Information

Manufacturer: Andon Health Co., Ltd.

Device: Connect App for iHealth Next

510(k) Number: K181541

5. Device Description

The iCare APP is a mobile application on both Android and iOS platforms.iCare allows users to better manage their own health by enabling them to measure their vital signs, access their results and relevant health information with just their smart device and internet connection, and receive feedback from their professional care team.

iCare includes a patient darshboard featuring the Home, Health, Plus, Education, and Profile tabs. Accessory devices can be connected to the system to allow for collection of blood sugar, blood pressure, blood oxygen, and/or weight measurements. The patient darshboard functionality includes the ability to start measuring, allows users to view and track measurements, and export testing schedules for blood

sugar, blood pressure, blood oxygen, and weight measurements; send messages to their professional care team; view previous appointment history information; view medication instructions; add entries to the food diary and review feedback from their registered dietician; set timers; and access articles and videos about health knowledge.

6. Intended Use

The iCare APP is intended for use in the home and clinical settings as an aid for users and their healthcare professionals to view test results which are measured by iHealth devices to better manage users' health and get feedback from their professional care team.

The iCare APP can also connect to medical devices and/or non-medical devices and get data from devices during measurement or from the data stored in the memory of the device for enhanced data management. Data can be transmitted, displayed, and stored in the APP.

7. Summary Comparing Technological Characteristics with Predicate Device iCare - Substantial Equivalence Comparison Tabular Format

Feature	**Subject Device** iCare	**Predicate Device** Connect App for iHealth Next	**Comparison**
Regulatory and Intended Use Comparison			
510(k) Number	N/A	K181541	N/A
Product Code and Classification Name	MWI, DXN, OCH, PUH, OUG, NBW	MWI, DXN, MNW, DQA	Similar: the connected devices are the same, OCH is product code for sportoximeter, and PUH is new product code for body analyzer exempt from 510(k). DQA is product code for medical oximeter needs 510(k), and MNW is product code for body analyzer needs 510(k). OUG and NBW is applicable to iCare with glucose data transmission, display and storage.
Class	Class II	Class II	Same
Regulation	MWI: Sec. 870.2300 Cardiac monitor (including cardiotachometer and rate alarm). DXN: Sec. 870.1130 Noninvasive blood pressure measurement system. OCH: Sec. 870.2700 Oximeter. PUH: Sec. 870.2770 Impedance	MWI: Sec. 870.2300 Cardiac monitor (including cardiotachometer and rate alarm). DXN: Sec. 870.1130 Noninvasive blood pressure measurement system. MNW: Sec. 870.2770 Impedance plethysmograph. DQA: Sec. 870.2700	OUG and NBW is added for the glucose meter data transmission, display and storage.

	plethysmograph. OUG: 880.6310 Medical device data system NBW: 862.1345 Glucose test system	Physiological signal amplifier.	
Indications for Use	The iCare APP is intended for use in the home and clinical settings as an aid for users and their healthcare professionals to view test results which are measured by iHealth devices to better manage users' health and get feedback from their professional care team. The iCare APP can also connect to medical devices and/or non-medical devices and get data from devices during measurement or from the data stored in the memory of the device for enhanced data management. Data can be transmitted, displayed, and stored in the APP.	The Connect App for iHealth Next is intended for use in home settings as an aid for people to view vital signs which are measured by iHealth devices (noninvasive blood pressure monitor and pulse oximeter). The Connect App for iHealth Next should not be used to either self-diagnose a disease state or exclude it. Please consult your physician if you find the reading is above a normal threshold.	Similar: Both devices are used to manage patient data. Both devices make no interpretation, evaluation, medical judgments, or recommendations for treatment. Clinical judgment and experience are required to check and interpret the information transmitted, and they are not intended as a substitute for medical care.
Patient Population	Home users	Home user	Same
Prescription Use (Rx)/ Over The Counter (OTC)	OTC	OTC	Same
Technological and Performance Characteristics			
Fundamental Technology	Software Only	Software Only	Same
Software Platform	iOS and Android	iOS and Android	Same
User Interfaces	Patient Portal	Patient Portal	Same
Biometric Parameters	Blood Pressure, Weight, Blood Glucose, and Pulse Oximeter Blood Glucose concentration	Blood Pressure, Weight, Pulse Oximeter	Similar: Other biometric parameters are either not medical devices or class I or II 510(k) exempt. The subject device can also be identified as MDDS, with function of display and store blood glucose result from glucose meter.
Data Collection	Wireless Bluetooth and manual entry	Wireless Bluetooth	Similar: Manual entry is not a medical device functionality.

Educational Articles	Access to patient education articles	None	Similar: Educational article functionality is not a medical device functionality.

Note: N/A indicates Not Applicable

8. Performance Summary Non-

Non-Clinical Test

Software Verification and Validation

Software verification and validation has been performed according to FDA guidance “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” . The iCare App software was considered a "moderate" level of concern since a failure or latent flaw in the software could result in minor injury to the patient or operator.

Wireless Coexistence Test

Wireless coexistence test has been performed to verify that the subject device can be used in intended environments.

Cybersecurity

Cybersecurity activities were conducted in accordance with FDA Guidance for Industry and FDA Staff, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions." The iCare App underwent appropriate risk-based cybersecurity assessment and testing in accordance with referenced FDA guidance documents.

Usability Testing

Usability testing was conducted in accordance with FDA guidance, “Applying Human Factors and Usability Engineering to Medical Devices”. The test result demonstrates that the iCare App can be used by lay users with only provided labeling, the device is safe and effective for the intended use.

Clinical Test

This section is not applicable.

9. Comparison to the Predicate Device and the Conclusion

The iCare APP is similar to the predicate device Connect App for iHealth Next. The nonclinical tests all passed the test conditions and demonstrated the iCare APP is as safe and as effective compared to the predicate device.