February 1, 2019

Andon Health Co., Ltd
Yi Liu
President
No. 3 Jinping Street, Ya An Road
Nankai District
Tianjin 300190 China

Re: K181070
Trade/Device Name: iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+)
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: December 24, 2018
Received: December 27, 2018

Dear Yi 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 and Part 809); 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,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181070

Device Name

iHealth Wireless Smart Gluco-Monitoring System（iHealth Gluco+）

Indications for Use *(Describe)*

The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) consists of the iHealth Wireless Smart Glucose Meter (BG5S) and the iHealth Blood Glucose Test Strips (EGS-2003). The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh. The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) is intended to be used by a single person and should not be shared.

The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

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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510(k) Summary

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

510(k) Number: k181070

1.0 submitter's information

Name: Andon Health Co., Ltd.

Address: No.3 Jinping Street,Ya'an Road, Nankai District, Tianjin, P.R. China

Phone number: 86-22-87611660

Fax number: 86-22-6052 6162

Contact: Yi Liu

Date of Preparation: 4/18/2018

2.0 Device information

Trade name: iHealth Wireless Smart Gluco-Monitoring System（iHealth Gluco+）

Common name: Blood Glucose Monitoring System

Classification name: Blood Glucose Monitoring System

3.0 Classification

Product code	classification	Regulation section	Panel
NBW	II	862.1345	Chemistry(75)

4.0 Predicate device information

Manufacturer: Andon Health Co., Ltd.

Device: iHealth BG5 WIRELESS SMART GLUCOSE MONITORING SYSTEM

510(k) number: K170231

5.0 Test principle

The blood glucose Monitoring System consist of blood glucose meter, single use test strips, sterile lancets, lancing device and the control solutions.

They are based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. For EGS-2003 test strip, the reactive enzyme is glucose dehydrogenase.

Capillary action at the end of the test strip draws the blood into the action chamber and the glucose in blood will take electrochemical reaction with the enzyme, the blood glucose result is displayed in 5 seconds.

6.0 Device description

The iHealth Wireless Smart Gluco-Monitoring System （ iHealth Gluco+ ） consist of BG5S glucose meter, EGS-2003 test strip, iHealth® control solution(Level I, Level II, Level III), lancet and lancing device. The BG5S glucose meter can display test result on meter itself, and can also be connected to iOS device and Android device through bluetooth and display test result on iOS or Android device.

7.0 Intended use

The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) consists of the iHealth Wireless Smart Glucose Meter (BG5S) and the iHealth Blood Glucose Test Strips (EGS-2003). The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh. The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) is intended to be used by a single person and should not be shared.

The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

8.0 Summary comparing technological characteristics with predicate device

Specification Comparison

CHARACTERISTICS	PREDICATE	NEW DEVICE
	BG5 BGMS (K170231)	BG5S BGMS
Detection Method	Amperometry	Same as predicate
Enzyme	Glucose Oxidase and Glucose dehydrogenase	Glucose dehydrogenase
Type of Meter	Biosensor (Electrode)	Same as predicate
Sample Source	Capillary whole blood from AST(Alternative site testing) and finger	Same as predicate
Sample Application	Blood sample is placed directly to the test strip after finger or AST is lanced.	Same as predicate
Hematocrit Range	20-60%	Same as predicate
Operating Temperature Range	10℃～40℃(50°-104°F)	10℃～40℃(50°-104°F)
Dimensions	9mm × 34.5mm ×19mm	Same as predicate BG5
Display	LED display, Connect to iOS device and android device to display measurement results	Same as predicate, except the LED color is changed
Result Presentation	mg/dL or mmol/L	Same as predicate
Memory Capabilities	500 times with time and date displaying	Same as predicate BG5
Test Start	Automatic	Same as predicate
Test Time	5 second	Same as predicate
Power Source	DC 3.7V d.c. li-ion 250mAh	Same as predicate BG5
Measurement Range	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)	50mg/dL-600mg/dL (2.8mmol/L~33.3mmol/L)
Qualified Test Strip	EGS-2003 and AGS-1000I Test Strip	EGS-2003
Sample Volume	Minimum 0.7 micro liter	Same as predicate
Connect Method	Connect to iOS device and Android device through bluetooth 3.0 wireles radio technology	Connect to iOS device and Android device through bluetooth 4.0 wireles radio technology;

Discussion of Non-Clinical Tests Performed

• Performance, functionality, and reliability of the proposed device has been evaluated. The performance evaluation include precision, altitude, temperature & humidity, linearity, interference, sample volume and hematocrit.

• Software: documentation was prepared and submitted for a moderate level of concern device in accordance with FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices;

Discussion of Clinical Tests Performed

User Evaluation was completed for the iHealth Wireless Smart Gluco-Monitoring System（iHealth Gluco+）. The study results demonstrate that the user accuracy and ease of use (via participant questionnaire scoring) confirmed the proposed device to be substantially equivalent to the predicate device.

9.0 Comparison to the predicate device and the conclusion

The proposed device is similar with the predicate device, they are both for single patient use, can test the blood glucose at the alternative site. The hematocrit range, the altitude and the use function are all the same, and all the proposed device can be connected to not only the iOS device, but also the Android device.

Compared the predicate device, BG5S connect to iOS device and Android device through bluetooth 4.0 wireles radio technology, which is different from the predicate device, and new mobile phone is added to the device. BG5S only declare to use one qualified test strip.

More over, the LED display color of BG5S is change, and the declared measurement range is also changed.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.