DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 4, 2015

ANDON HEALTH CO., LTD
YI LIU, PRESIDENT
NO 3, JINPING RD, YA AN ST
NANKAI DISTRICT
TIANJIN 300193 CHINA

Re: K150833
Trade/Device Name: iHealth Align Gluco-Monitoring System
iHealth BG5L wireless Smart Gluco-Monitoring System
iHealth BG5 wireless Smart Gluco-Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JQP
Dated: November 2, 2015
Received: November 4, 2015

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. 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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education 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 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 yours,

Katherine Serrano -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)*
k150833

Device Name
iHealth Align Gluco-Monitoring System

Indications for Use *(Describe)*
The iHealth Align Gluco-Monitoring System consists of the iHealth Align Glucose meter (BG1), iHealth Blood Glucose Test Strips (AGS-1000I), and the iHealth Gluco-Smart App mobile application as the display component of the iHealth Align Gluco-Monitoring System. The iHealth Align Gluco-Monitoring System 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 Align Gluco-Monitoring System is intended to be used by a single person and should not be shared.

The iHealth Align Gluco-Monitoring System 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 Align Gluco-Monitoring System 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.

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
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
k150833

Device Name
iHealth BG5 wireless Smart Gluco-Monitoring System

Indications for Use *(Describe)*

The iHealth BG5 wireless Smart Gluco-Monitoring System 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 BG5 wireless Smart Gluco-Monitoring System is intended to be used by a single person and should not be shared.

The iHealth BG5 wireless Smart Gluco-Monitoring System 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 BG5 wireless Smart Gluco-Monitoring System 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).

The AGS1000I test strips are for use with the iHealth BG5 meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k150833

Device Name
iHealth BG5L wireless Smart Gluco-Monitoring System

Indications for Use *(Describe)*

The iHealth BG5L wireless Smart Gluco-Monitoring System 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 BG5L wireless Smart Gluco-Monitoring System is intended to be used by a single person and should not be shared.

The iHealth BG5L wireless Smart Gluco-Monitoring System 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 BG5L wireless Smart Gluco-Monitoring System 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).

The AGS1000I test strips are for use with the iHealth BG5L meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.

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.

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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.

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Road, Ya'an street TIANJIN,300193
Phone number: 86-22-60526161
Fax number: 86-22-6052 6162
Contact: Yi Liu
Date of Application: 3/20/2015

2.0 Device information

Device name: iHealth Align Gluco-Monitoring System
iHealth BG5 wireless Smart Gluco-Monitoring System
iHealth BG5L wireless Smart Gluco-Monitoring System

Classification name: Blood Glucose Monitoring System

3.0 Classification

Product code	Classification	Regulation Section	Panel
NBW	II	21 CFR 862.1345	Chemistry (75)
CGA	II	21 CFR 862.1345	Chemistry (75)
JQP	I	21 CFR 862.2100	Chemistry (75)

4.0 Predicate device information

Manufacturer: Andon Health Co., Ltd.

Device: iHealth Align Mini Gluco-Monitoring System

510(k) number: K133790

5.0 Device description

The iHealth Align Gluco-Monitoring System consists of a blood glucose

meter, test strips, iHealth Gluco-Smart App, sterile lancets, lancing device and AGS-1000I Control Solutions (Level I, Level II and Level III). The iHealth Align Gluco-Monitoring System cannot display test results and must be used with an iPhone or iPod touch via an 3.5 mm auxiliary jack.

The iHealth BG5 wireless Smart and iHealth BG5L wireless Smart Gluco-Monitoring Systems consist of the BG5 and BG5L wireless Smart blood glucose meters, respectively, AGS-1000I Test Strips , sterile lancets, lancing device and the iHealth control solutions control solutions. (Control solutions provided are for Level 1, II, and III). iHealth BG5L uses Bluetooth 4.0 wireless radio technology; while iHealth BG5 uses Bluetooth 3.0 wireless radio technology. The iHealth BG5 and BG5L meters can display the test results and the test results can also be transmitted to an iPhone, iPod touch or iPad through blue tooth.

iHealth Gluco-Smart App is iOS- based software for use with the iHealth Align Glucose meter (BG1), iHealth BG5 meter, and iHealth BG5L meter. When used with these meters, iHealth Gluco-Smart App acts as a display and allows command and control of the meter. The App can transfer data from the device's memory, manage, and share the data.

6.0 Intended use

The iHealth Align Gluco-Monitoring System consists of the iHealth Align Glucose meter (BG1), iHealth Blood Glucose Test Strips (AGS-1000I), and the iHealth Gluco-Smart App mobile application as the display component of the iHealth Align Gluco-Monitoring System. The iHealth Align Gluco-Monitoring System 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 Align Gluco-Monitoring System is intended to be used by a single person and should not be shared.

The iHealth Align Gluco-Monitoring System 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 Align Gluco-Monitoring System 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).

The iHealth BG5 wireless Smart Gluco-Monitoring System 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 BG5 wireless Smart Gluco-Monitoring System is intended to be used by a single person and should not be shared.

The iHealth BG5 wireless Smart Gluco-Monitoring System 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 BG5 wireless Smart Gluco-Monitoring System 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).

The AGS-1000I test strips are for use with the iHealth BG5 meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.

The iHealth BG5L wireless Smart Gluco-Monitoring System 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 BG5L wireless Smart Gluco-Monitoring System is intended to be used by a single person and should not be shared.

The iHealth BG5L wireless Smart Gluco-Monitoring System 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 BG5L wireless Smart Gluco-Monitoring System 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).

The AGS-1000I test strips are for use with the iHealth BG5L meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.

7.0 Summary comparing technological characteristics with predicate device

Item	Predicate device	Candidate Devices

Item	Predicate device	Candidate Devices	
Device name	iHealth Align Mini Gluco-Monitoring System	iHealth BG5L wireless Smart Gluco-Monitoring System and iHealth BG5L wireless Smart Gluco-Monitoring System	iHealth Align Gluco-Monitoring system
IFU	Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip palm, forearm, upper arm, calf, or thigh	Same	same
Model	BG1	BG5 (Bluetooth) BG5L (Bluetooth low energy)	Same
Enzyme	Glucose oxidase	same	same
Measuring range	20 – 600 mg/dL	Same	Same
Hematocrit range	20-60%	Same	same
Connectivity to Meter	Earphone jack	Same and Bluetooth and Bluetooth low energy	Earphone jack
Display	Connect to Apple platform	Same and LED meter display	Same
Test Strip Calibration	QR code scan	Same	Same
Dimensions	52 mm×30 mm×9.5 mm	9 mm × 34.5mm ×19mm	Same
Mobile App name	iHealth Gluco-Smart App	Same	Same
Mobile App version	V2.3	V3.8.5	V3.8.5
Compatible iOS version	5, 6, 7	7, 8, 9	7, 8, 9

Item	Predicate device	Candidate Devices	
Phone Platform	iPhone 5s iPhone 5c iPhone 5 iPhone 4S iPhone 4 iPhone 3GS iPod touch (4th generation) iPod touch (5th generation)	Same and iPhone 6S iPhone 6S Plus iPhone 6 iPhone 6 PLUS iPad2 iPad3 iPad4 iPad Mini iPad mini 2 iPad Air iPad Air 2	Same and iPhone 6S iPhone 6S Plus iPhone 6 iPhone 6 PLUS

8.0 Performance summary

Software validation and user study has been performed to establish the performance, the functionality and the reliability characteristics of the new device. Testing of iHealth Gluco-Smart App included system test and unit test.

9.0 Comparison to the predicate device and the conclusion

The proposed device is similar with the predicate device iHealth BG1, they are both for single patient use, they use the same test strip, and can test the blood glucose at the alternative site. The hematocrit range, the altitude and the use function are all the same. However, the proposed devices, BG1, BG5/BG5L systems can be operated with the claimed platforms.

iHealth Gluco-Smart App can operate with both iHealth BG1 Align Gluco-Monitoring System and iHealth BG5/BG5L wireless Smart Gluco-Monitoring System, The style of the app are also changed. Some new function are added ,such as A Blood Glucose summary according to the data saved in database should be displayed, People can share the data by Facebook.

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