



ANDON HEALTH CO., LTD
LIU YI, PRESIDENT
NO. 3 JINPING STREET, YA AN ROAD, NANKAI DISTRICT
TIANJIN, P.R. CHINA

August 19, 2016

Re: K153286
Trade/Device Name: iHealth Align Gluco-Monitoring System (BG1)
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JQP
Dated: August 11, 2016
Received: August 15, 2016

Dear Mr. Yi:

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,


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For : Courtney H. Lias
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known)
k153286

Device Name

iHealth Align Gluco-Monitoring System (BG1)

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.

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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 Street, Ya'an Road, Nankai District, Tianjin, P.R. China
Phone number: 86-22-6052 6161
Fax number: 86-22-6052 6162
Contact: Yi Liu
Date of Preparation: 11/05/2015

2.0 Device information

Trade name: iHealth Align Gluco-Monitoring System (BG1)
Common name: Blood Glucose Monitoring System
Classification name: Blood Glucose Monitoring System

3.0 Classification

Production code: NBW- Blood Glucose Monitoring System.
Regulation number: 862.1345
Classification: II
Panel: Clinical Chemistry

Production code: CGA- test, blood glucose, over the counter
Regulation number: 862.1345
Classification: II
Panel: Clinical Chemistry

Production code: JQP
Regulation number: 862.2100
Classification: I
Panel: Clinical Chemistry

4.0 Predicate device information

Manufacturer: Andon Health Co., Ltd.

Device: iHealth Align mini Gluco-Monitoring System(BG1)

510(k) number: K133790

5.0 Device description

The iHealth Align Gluco-Monitoring System(BG1) 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. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 5 seconds. The control solution available is used to test the performance of the device. It uses the same technological characteristics for testing with its predicate device.

In order to use the iHealth Align Gluco-Monitoring system(BG1) , a compatible Android or iOS mobile device with the necessary mobile application installed is required.

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).

7.0 Summary comparing technological characteristics with predicate device

CHARACTERISTICS	NEW DEVICE: iHealth Align Gluco-Monitoring System(BG1)	PREDICATE: iHealth BG1 Align mini Gluco-Monitoring System (K133790)
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Type of Meter	Biosensor (Electrode)	Biosensor (Electrode)
Sample Source	Capillary whole blood from AST(Alternative site testing) and finger	Capillary whole blood from AST(Alternative site testing) and finger
Sample Application	Blood sample is placed directly to the test strip after finger or AST is lanced.	Blood sample is placed directly to the test strip after finger or AST is lanced.
Hematocrit Range	20-60%	20-60%
Operating Temperature Range	10°C ~ 35°C (50°-95°F)	10°C ~ 35°C (50°-95°F)
Dimensions	52mm×30mm×9.5mm	52mm×30mm×9.5mm
Display	Connect to iOS device and android device to display measurement results	Connect to iOS device to display measurement results
Result Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Memory Capabilities	10000 times with time and date displaying	10000 times with time and date displaying
Test Start	Automatic	Automatic
Test Time	5 second	5 second
Power Source	DC3.0V (CR1620)	DC3.0V (CR1620)
Battery Life	N/A	N/A
Measurement Range	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)
Qualified Test Strip	AGS-1000I Test Strip	AGS-1000I Test Strip
Sample Volume	Minimum 0.7 micro liter	Minimum 0.7 micro liter

Connect Method	Connect to iOS device and Android device through Earphone jack	Connect to iOS device through Earphone jack
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8.0 Comparison to the predict 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 device can be connected to not only the iOS device, but also the Android device.

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