510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k150833

B. Purpose for Submission:

Modified devices to add compatibility with additional mobile platforms; see device comparison table in section J, below.

C. Measurand:

Capillary Whole Blood Glucose from the fingertip palm, forearm, upper arm, calf or thigh

D. Type of Test:

Quantitative, amperometric method, glucose oxidase

E. Applicant:

Andon Health Co., Ltd

F. Proprietary and Established Names:

iHealth Align Gluco-Monitoring System
iHealth BG5 wireless Smart Gluco-Monitoring System
iHealth BG5L wireless Smart Gluco-Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345 - Glucose test system
   21CFR 862.2100 - Calculator/data processing module for clinical use

2. Classification:

   Class II
   Class I, exempt

3. Product code:

   NBW - system, test, blood glucose, over the counter

CGA - Glucose Oxidase
JQP - calculator/data processing module, for clinical use

4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
See indications for use, below.

2. Indication(s) for use:

iHealth Align Gluco-Monitoring System

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).

iHealth BG5 wireless Smart Gluco-Monitoring System

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.

iHealth BG5L wireless Smart Gluco-Monitoring System

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.

3. Special conditions for use statement(s):

For the iHealth Align, iHealth BG5 wireless Smart, and iHealth BG5L wireless Smart Gluco-Monitoring Systems:

- Not intended for use on neonates.
- Not intended for use on artery blood, serum, and plasma.
- For single patient use.
- Should not be used for the diagnosis of or screening for diabetes
- Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Not for use on critically ill patients.
- Not for patients who are dehydrated, hypertensive, hypotensive, or in shock.
- Very low or very high red blood cell count (hematocrit) can lead to incorrect test results.
- AST should be used only during steady-state times when blood glucose levels are not changing rapidly.
- Alternate Site Testing should not be used to calibrate continuous glucose monitoring systems (CGMs).
- Results from Alternate Site Testing should not be used in insulin dose calculations.

4. Special instrument requirements:

iHealth Align Glucose meter (BG1)
iHealth BG5 meter

iHealth BG5L meter

I. 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 AGS1000I 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, Apps-AG01 iHealth 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   iHealth Align Mini Gluco-Monitoring System

2. Predicate 510(k) number(s):

   k133790

3. Comparison with predicate:

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

Item	Predicate device	Candidate Devices	
IFU	Is intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	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	Bluetooth and Bluetooth low energy	Earphone jack
Display	Connect to Apple platform	Connect to Apple platform 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	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)	iPhone 5s iPhone 5c iPhone 5 iPhone 4S iPhone 4 iPhone 3GS iPod touch (4th generation) iPod touch (5th generation) iPhone 6S iPhone 6S Plus iPhone 6 iPhone 6 PLUS iPad2 iPad3 iPad4 iPad Mini iPad mini 2 iPad Air iPad Air 2	iPhone 5s iPhone 5c iPhone 5 iPhone 4S iPhone 4 iPhone 3GS iPod touch (4th generation) iPod touch (5th generation) iPhone 6S iPhone 6S Plus iPhone 6 iPhone 6 PLUS

K. Standard/Guidance Document Referenced (if applicable):

None

L. Test Principle:

The iHealth Align Gluco-Monitoring System, iHealth BG5 Wireless Smart Gluco-Monitoring System, and BG5L Wireless Smart Gluco-Monitoring Systems 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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

      As established in k110017

   b. *Linearity/assay reportable range:*

      As established in k110017

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Traceability:
The system is traceable to the NIST SRM 917 glucose reference material.
Traceability was evaluated in k110017.

Test Strip Stability:
The AGS-1000I blood glucose test strips are identical to the test strips in the predicate device, iHealth Align Mini Gluco-Monitoring System (BG1 - k133790). Stability protocols and acceptance criteria were reviewed in k110017 and support the sponsors claimed shelf life of 24 month shelf-life when stored at 39 to 86°F (2-30°C) with relative humidity of <80% and a 90 day stability after opening when stored at 39 to 86°F with relative humidity of <80 %.

Control Solution Stability:
The iHealth control solutions are identical to the control solutions in the predicate device (k133790). Value assignment and stability protocols and acceptance criteria were reviewed in k110017 and support the sponsors claimed shelf life of 24 month shelf-life when stored at 39 to 86°F (2-30°C) with relative humidity of <80% and a 90 day stability after opening when stored at 39 to 86°F with relative humidity of <80 %.

d. *Detection limit:*

The reportable range is 20 to 600 mg/dL based on the linearity/assay reportable range study above (section M.1.).

e. *Analytical specificity:*

As established in k110017

f. *Assay cut-off:*

Not applicable

2. Comparison studies:
   a. *Method comparison with predicate device:*

   As established in k110017

   b. *Matrix comparison:*

   Not applicable

3. Clinical studies:
   a. *Clinical Sensitivity:*

   Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

As established in k110017

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Time of day	People without diabetes
Fasting and before meals	<100 mg/dL
2 hours after meals	<140 mg/dL

(American Diabetes Association: Diagnosis and Classification of Diabetes Mellitus (Position Statement). Diabetes Care 36 (Supp. 1) S71, 2013.

N. Instrument Name:

iHealth Align Gluco-Monitoring System
iHealth BG5 wireless Smart Gluco-Monitoring System
iHealth BG5L wireless Smart Gluco-Monitoring System

O. System Descriptions:

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes ____X____ or No _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes ___X_____ or No _____

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for

this line of product types:

Yes ___X_____ or No _____

3. Specimen Identification:

   Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   This device is intended to be used with capillary whole blood from AST (Alternative site testing, including palm, forearm, upper arm, calf, or thigh) and finger.

5. Calibration:

   The user scans a QR code to code the test strips. The App controls the platform's camera. The QR scan code App function was successfully validated on representative Apple platforms for the BGL, BG5 and BG5L meters.

6. Quality Control:

   The iHealth Control solution are used as a quality control checks to make sure that the iHealth Align Gluco-Monitoring System (BG1) and iHealth BG5/5L Wireless Smart Gluco-Monitoring Systems and the AGS-1000I blood glucose test strips are working correctly. The labeling provides instructions on when quality control testing should be performed.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. **Software:** Software documentation was reviewed and demonstrated that the device was developed under appropriate software lifecycle processes.

2. **Electromagnetic compatibility (EMC)** (radiated emissions and immunity) testing: As established in k120813

3. **Usability Questionnaire:** Using representative Apple platforms, a 40 participant study was conducted to verify users with average education and computer skills and no prior knowledge of the system can use the new device without direct instruction or training. Study results demonstrated that participants rated the ease of use of the devices as normal or above.

4. **Data transmission accuracy:** Demonstrated, using representative Apple platforms and 5 of each meter (iHealth Align, iHealth BG5 and BG5L), that sent and received data matched.

5. **Infection Control and Robustness Studies:**

   The iHealth Align Gluco-Monitoring System, iHealth BG5 Wireless Smart Gluco-Monitoring System, and BG5L Wireless Smart Gluco-Monitoring System are intended for single-patient use. The sponsor stated that the disinfection efficacy for the meters was established in k110017 (BG5 and BG5L) and in k123935 (Align Mini) and that the materials comprising the candidate meters are identical. CaviWipes Disinfecting Towelettes (EPA registration #46781-8) were previously validated through disinfection efficacy studies demonstrating complete inactivation of hepatitis B (HBV) virus using materials comprising the meter.

   Robustness testing was previously established in k133790 (Align Mini) and k123935 (BG5 and BG5L) demonstrating that there was no change in performance or in the external materials of the meter after 11,000 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

   The sponsor provides a disposable sleeve for use with the iPod or iPhone to be used with each test strip, not to be reused and to be disposed of as bio-hazard, therefore no disinfection studies were required of the iPod or iPhone. The sleeve is intended to be used with the iHealth Align Gluco-Monitoring System.

6. **Hematocrit**: As established in k110017

7. **Altitude**: As established in k110017

8. **Temperature and Humidity operating conditions:** As established in k110017

9. **Sample volume:** As established in k110017

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.