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

A. 510(k) Number:

k153286

B. Purpose for Submission:

Modified devices to add compatibility with Android mobile platforms

C. Measurand:

Capillary whole blood glucose from the finger, palm, forearm, upper arm, calf, or thigh

D. Type of Test:

Quantitative, amperometric assay, glucose oxidase

E. Applicant:

Andon Health Co., Ltd.

F. Proprietary and Established Names:

iHealth Align Gluco-Monitoring System (BG1)

G. Regulatory Information:

Regulation	Name	Class	Product Code	Panel
21 § 862.1345	Glucose test system	II	NBW	(75) Chemistry
21 § 862.1345	Glucose Oxidase	II	CGA	(75) Chemistry
21 § 862.2100	Calculator/data processing module for clinical use	I	JQP	(75) Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for 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).

3. Special conditions for use statement(s):

- Not for use in critically ill patients
- Not for neonatal use
- Not intended for use on arterial blood, serum, or plasma
- Patients undergoing oxygen therapy may show results lower than actual levels.
- AST should be done only during steady state times when glucose levels are not changing rapidly.
- Do not perform AST if you think your glucose is low, you are unaware that you might have hypoglycemia, you are testing for hyperglycemia, your AST results do not match the way you feel, your routine glucose results fluctuate often
- Do not use AST results to calibrate a continuous glucose monitor (CGM)
- Do not use AST results for insulin dosing calculations
- This device is not for use in people who are severely dehydrated, in people who are severely hypotensive, or people who are in shock, consult your healthcare professional immediately when this happens.
- Not for use in individuals who are in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Use only fresh capillary whole blood samples.
- Very low or very high red blood cell count (hematocrit) can lead to incorrect test results. If you do not know your hematocrit level, please consult your healthcare provider.
- For over-the-counter use
- If you take acetaminophen or acetaminophen containing medications (Tylenol, certain cold and flu remedies, or certain prescription drugs) higher than the recommended levels (>5 mg/dL) then you should know that this medication might affect the reliability of your blood glucose results and you should not use this Blood Glucose Monitoring System. If you are unsure, than ask your doctor.

- Certain conditions may cause your blood level of uric acid to rise. These conditions include gout or kidney disease. Uric acid levels in your blood are measured by a laboratory test that your doctor orders. You should know that if your blood level of uric acid is high (≥10 mg/dL) then your blood glucose results may be not reliable. If your doctor tells you that your uric acid level is greater than 10 mg/dL, then do not use this blood glucose monitoring system. If you are unsure, then ask your doctor.
- Vitamin C (Ascorbic acid (>2 mg/dL) naturally in your blood or from food or taking Vitamin C supplements might cause inaccurate blood glucose results when using this blood glucose monitoring system.

4. Special instrument requirements:

   iHealth Align Glucose Meter (BG1)

I. Device Description:

The iHealth Align Gluco-Monitoring System (BG1) consists of a blood glucose meter, single use test strips, sterile lancets, lancing device, and control solutions. The test system is based on an electrochemical biosensor and the principal of capillary action. Capillary action at the end of the test strip draws the blood into the test chamber and the blood glucose result is displayed in 5 seconds. Control solution is available to be used to test the performance of the device. The iHealth Align blood glucose meter must be used with a compatible mobile device (either iOS or Android). A mobile app installed on the mobile device serves as the display for the iHealth Align blood glucose meter. The iHealth Align blood glucose meter must be plugged into a compatible mobile device via the 3.5mm audio port, and the iHealth mobile app must be running in order for a blood glucose measurement to be performed; a measurement cannot be performed if the iHealth Align blood glucose meter is not connected to the audio port on the mobile device with the mobile app running.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   iHealth BG1 Align Mini Gluco-Monitoring System

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

   k133790

3. Comparison with predicate:

Similarities		
Item	Predicate Device iHealth BG1 Align Mini Gluco-Monitoring System (k133790)	Candidate Device iHealth Align Gluco-Monitoring System (BG1) (k153286)
Indications for Use	Intended for the quantitative measurement of glucose in fresh capillary blood samples by people with diabetes at home to monitor the effectiveness of diabetes control	Same
Test Principle	Amperometry	Same
Hematocrit Range	20-60%	Same
Measuring Range	20-600 mg/dL	Same
Sample Volume	0.7 μL	Same
Test Time	5 seconds	Same
Coding	Code scanning via cell phone camera	Same
Control Solutions	AGS1000I Control Solutions (Level I, Level II and Level III)	Same
Altitude	10744 ft	Same
Operating Temperature Range	10-40ºC	Same
Power Source	DC 3.0V (CR1620) battery	Same
Alternative Site Testing	Palm, forearm, upper arm, calf, or thigh	Same

Differences		
Item	**Predicate Device** iHealth BG1 Align Mini Gluco-Monitoring System (k133790)	**Candidate Device** iHealth Align Gluco-Monitoring System (BG1) (k153286)
Connect Method	Connect to iOS device through Earphone jack	Connect to iOS device and Android device through Earphone jack
Phone Platform	iPhone 5s iPhone 5c iPhone 5 iPhone 4S iPhone 4 iPhone 3GS iPod touch (4th generation) iPod touch (5th generation) 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) iPad2 iPad3 iPad4 iPad Mini iPad Mini 2 iPad Air iPad Air 2Samsung Galaxy S6 Edge Samsung Galaxy S6 Samsung Galaxy S5 Samsung Galaxy S4 Samsung Galaxy S3 Samsung Galaxy Note3 Samsung Galaxy Note2 HTC One M7 LG Nexus 4 LG Nexus 5 Motorola Nexus 6

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

EN 60601-1-2:2007 Medical electrical equipment, Part 1: General requirements for basic safety and essential performance, collateral standard: electromagnetic compatibility

L. Test Principle:

The iHealth Align Gluco-Monitoring System (BG1) measures glucose amperometrically. The reaction of glucose oxidase and an electron mediator in the test strip with glucose in the sample produces an electrical current which is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration, which is displayed by the iHealth mobile app.

M. Performance Characteristics (if/when applicable):

The device is a modification of a cleared BG1 meter (k133790) to connect and provide the User Interface with Android mobile devices using the same test strip and control cleared with the BG1 meter in k133790. The meter, strip and analytical module are unchanged. The sponsor conducted necessary validation of the device, such as human factors testing and bench testing (see Section P).

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):

   As established in k110017, the system is traceable to NIST SRM #917c reference material and calibrated to be plasma-equivalent

   Control Solution Value Assignment and Stability:

   The iHealth Glucose Control Solutions Level I, Level II, and Level III were previously reviewed in k110017 and found to be acceptable. The control solutions have a 24 month shelf life from the date of manufacture when stored at 39 to 86ºF (4-30ºC) with relative humidity of 10-80% and a 90 day stability after opening when stored at 39 to 86ºF.

Test Strip Stability:

Test strip stability was assessed with accelerated studies and on-going real-time studies. The testing protocols and acceptance criteria were reviewed and found to be acceptable. Testing for the test strips and control solutions supports the claimed shelf life of 24 months when stored at 39 to 86 ºF (4-30 ºC) with relative humidity of 10-80% and 90 day stability after opening when stored at 39 to 86 ºF.

d. Detection limit:

As established in k110017

e. Analytical specificity:

As established in k110017

The sponsor performed interference studies with spiked venous blood samples at three glucose concentrations (~80, 120, and 350 mg/dL) that were prepared and divided into a test (dosed) pool and a control pool. The potential interferants (2 levels) were added to the sample and each sample was tested 5 times. The table below lists all substances tested at concentrations without significant (<10%) interference.

Substance	**Concentration with <10% interference (mg/dL)**
Acetaminophen	5.0
Ascorbic acid	2.0
Bilirubin	15 mg/dL
Ibuprofen	50 mg/dL
Dopamine	0.03 mg/dL
L-dopa	0.45 mg/dL
Methyldopa	0.75 mg/dL
Salycilate	60 mg/dL
Tolbutamide	24 mg/dL
Triglycerides	2000 mg/dL
Uric acid	10 mg/dL
Maltose	350 mg/dL
Xylose	100 mg/dL
Galactose	15.1 mg/dL
Lactose	100 mg/dL
Creatinine	17 mg/dL
Sodium	639 mg/dL (MW 58.5)
Hemoglobin	250 mg/dL

The following limitations for use are included in the labeling for this device:

If you take acetaminophen or acetaminophen containing medications (Tylenol, certain cold and flu remedies, or certain prescription drugs) higher than the recommended levels (>5 mg/dL) then you should know that this medication might affect the reliability of your blood glucose results and you should not use this Blood Glucose Monitoring System. If you are unsure, than ask your doctor.

Certain conditions may cause your blood level of uric acid to rise. These conditions include gout or kidney disease. Uric acid levels in your blood are measured by a laboratory test that your doctor orders. You should know that if your blood level of uric acid is high (≥10 mg/dL) then your blood glucose results may be not reliable. If your doctor tells you that your uric acid level is greater than 10 mg/dL, then do not use this blood glucose monitoring system. If you are unsure, then ask your doctor.

Vitamin C (Ascorbic acid (>2 mg/dL) naturally in your blood or from food or taking Vitamin C supplements might cause inaccurate blood glucose results when using this blood glucose monitoring system.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

As established in k110017

b. Matrix comparison:

Not applicable. Fresh capillary whole blood is the only acceptable matrix.

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):*

The sponsor performed a user performance study in k110017 to evaluate the performance of their device in 100 lay-users. The results of this testing are described in k110017.

The performance established in k110017 was confirmed by evaluating forty subjects using the iHealth BG1 Align blood glucose meter using 40 meters and 40 Android devices (10 each of three representative models). Each subject obtained his or her own fingertip capillary sample and performed a blood glucose control test using the iHealth BG1 Align blood glucose meter. A professional then collected a fingerstick blood sample to run on a laboratory reference method (YSI 2300). The results are described below:

User Performance Results comparing meter fingerstick results to YSI

Glucose Concentrations ≤75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
6/8	8/8	8/8
75%	100%	100%

Glucose Concentrations >75 mg/dL

Within ±5 %	Within ±10 %	Within ±15 %	Within ±20%
24/32	31/32	32/32	32/32
75%	97%	100%	100%

The sponsor conducted a linear regression analysis of the data collected for this confirmatory user performance study. The results are as follows:

Regression Equation	R^2
y = 1.049x – 2.061	0.9913

Usability Questionnaire: Using representative Android platforms, the 40 participants in the User Performance, who had average computer skills and no prior knowledge of the system, were assessed to determine if typical users 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. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:

   The sponsor included the following expected values for people without diabetes in the labeling:

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

   Source: American Diabetes Association: Classification and Diagnosis of Diabetes (Position Statement). Diabetes Care 39 (Supp. 1) S15, 2016.

N. Instrument Name:

iHealth Align Blood Glucose Meter (BG1)

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and must be replaced with a new strip for additional readings. Minimal sample volume is 0.7 µL per test.

   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 _____ or No ___X____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ____X___ or No _____

   The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the finger, palm, forearm, calf, and thigh only. The sample is applied directly to the test strip and testing is performed immediately. Sample storage is not required.

5. Calibration:

   Calibration of the meter occurs by scanning of a 2D barcode (QR Code) located on the top of the test strip vial by the built in camera of a smartphone that is used in conjunction with the device. The QR code must be scanned each time a new vial is opened.

6. Quality Control:

   Three levels of aqueous glucose control solutions are available with this system (level 1, level 2, level 3) but must be purchased separately. The meter automatically recognizes control materials as separate from patient samples and identifies them as control in the smartphone application where meter values are displayed and recorded. Controls are not included in patient glucose averaging. Recommendations on when to test the control materials and troubleshooting steps if the controls are outside of specifications are provided in the labeling. An acceptable range for each control level is printed on the test strip vial label.

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

1. Hematocrit study: As established in k110017, the claimed hematocrit range is 20-60%

2. Altitude study: As established in k110017, the claimed altitude is 10,744 ft.

3. Infection Control Study: The iHealth Align Gluco-Monitoring System (BG1) is intended for single-patient use. The sponsor stated that the disinfection efficacy for the meter was established in k123935 and that the materials comprising the candidate meter 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 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 mobile device 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 mobile device. The sleeve is intended to be used with the iHealth Align Gluco-Monitoring System.

4. Data Transmission Accuracy: Bench testing was performed to verify the transmission accuracy of electrical signals between the glucose meter and the representative Android devices. This evaluation consisted of the following: sending of data (output from glucose meter) and receiving of data (input into Android device). Data from the glucose meter and the receiving data on the Android device was in 100% agreement.

5. Environmental testing for temperature and relative humidity: As established in k110017. Operating temperature is from 10-40ºC with a relative humidity of 10-80%.

6. Sample volume requirements: As established in k110017. The minimum sample volume is 0.7 µL

7. EMC and electrical safety: As established in k110017.

8. Readability study: A readability evaluation was conducted which determined that the reading grade level is at the 8th grade level.

9. Customer support is available by calling 1-855-816-7705, 8:30 AM – 5:30 PM PST, Monday - Friday

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.