

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

A. 510(k) Number:

k153278

B. Purpose for Submission:

Modified devices to add compatibility with Android mobile platforms

C. Measurand:

Capillary Whole Blood Glucose from the fingertip 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 Wireless Smart Gluco-Monitoring System (BG5)

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 Wireless Gluco-Monitoring System consists of the iHealth Wireless Glucose meter (BG5), iHealth Blood Glucose Test Strips (AGS-1000I), and the iHealth Gluco-Smart App mobile application. The iHealth Wireless 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 Wireless Gluco-Monitoring System is intended to be used by a single person and should not be shared.

The iHealth Wireless 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 Wireless 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
- The iHealth system is not intended for use on neonates
- The iHealth system is not intended for use on arterial blood, serum, or plasma
- The following substances at levels greater than normal or therapeutic levels may cause significant interference (affect the result by greater than 10%), resulting in an inaccurate result: ascorbic acid, uric acid, acetaminophen, dopamine, L-dopa
- Do not use haemolysis samples, icterus samples, or high lipemia samples.
- 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
- 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
 - 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 Wireless Smart Glucose Meter (BG5)

I. Device Description:

The iHealth Wireless Smart Gluco-Monitoring System (BG5) consists of the iHealth Wireless Smart blood glucose meter (BG5), AGS 1000I Test Strips , sterile lancets, lancing device and the iHealth control solutions. Control solutions provided are for Level I, II, and III. The iHealth BG5 meter uses Bluetooth 3.0 Wireless radio technology. The iHealth BG5 meter can display the test results and the test results can also be transmitted to an Apple and Android based mobile device.

iHealth Gluco-Smart App is iOS and Android based software for use with the iHealth BG5 meter. When used with this meter, the 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.

Andon is modifying cleared test systems to add Android mobile device compatibility. The BG5 system has been cleared previously in k150833 with Apple-based hardware and software. The meter firmware has not changed. The system's AGS 1000I Test Strips are identical to the claimed predicate, k123935.

J. Substantial Equivalence Information:

1. Predicate device name(s):

iHealth BG5 Wireless Smart Gluco-Monitoring System

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

k123935

3. Comparison with predicate:

Similarities		
Item	Predicate Device iHealth BG5 Wireless Smart Gluco-Monitoring System (k123935)	Candidate Device iHealth Wireless Smart Gluco- Monitoring System (BG5) (k153278)
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
Sample Source	Capillary whole blood from fingertip, palm, forearm, upper arm, calf or thigh	Same
Model	BG5 (Bluetooth)	Same
Enzyme	Glucose oxidase	Same
Measuring range	20 – 600 mg/dL	Same
Hematocrit range	20-60%	Same
Connectivity to Meter	Bluetooth	Same
Test Strip Calibration	QR code scan	Same
Dimensions	9 mm × 34.5mm × 19mm	Same
Mobile App name	iHealth Gluco-Smart App	Same

Differences		
Item	Predicate Device iHealth BG5 Wireless Smart Gluco-Monitoring System (k123935)	Candidate Device iHealth Wireless Smart Gluco- Monitoring System (BG5) (k153278)
Mobile App	V2.1	V3.4.3
Compatible OS version	iOS 5, 6, 7	iOS 7, 8, 9 Android 4.0, 4.2, 4.4, 5.0
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 2 Samsung 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
Display	Connect to Apple platform and LED meter display	Connect to Apple, and Android platforms and LED meter display

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

EN 60601-1-2:2007 – Medical electrical equipment, general requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility

L. Test Principle:

The iHealth Wireless Smart Gluco-Monitoring System (BG5) 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 meter.

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):*

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

Test Strip Stability:

The AGS-1000I blood glucose test strips are identical to the test strips in the predicate device, iHealth BG5 Wireless Smart Gluco-Monitoring System (k123935). 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 (4-30°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 Glucose Control Solutions Level I, Level II, and Level III were previously reviewed in k123935. The control solutions have shelf life of 24 months from the date of manufacture when stored at 39 to 86°F (4-30°C) with relative humidity of 10-80% and a 90 day stability after opening when stored at 39 to 86°F.

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
Salicylate	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 demonstrate the accuracy of the system in the hand of the intended 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
7/10	10/10	10/10
70%	100%	100%

Glucose Concentrations > 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
21/30	29/30	30/30	30/30
70%	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
$y = 1.033x - 1.169$	0.9872

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 Wireless Smart Gluco-Monitoring System (BG5)

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:

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:

The iHealth Control solution are used as a quality control checks to make sure that the iHealth BG5 Wireless Smart Gluco-Monitoring System 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 k123935
3. **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.
4. **Infection Control and Robustness Studies:**
iHealth Wireless Smart Gluco-Monitoring System (BG5) is intended for single-patient use. The sponsor stated that the disinfection efficacy for the meters was established in k110017 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 k123935, 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.
5. **Hematocrit:** As established in k123935, the claimed hematocrit range is 20-60%
6. **Altitude:** As established in k123935, the claimed altitude is 10,744 ft.
7. **Temperature and Humidity operating conditions:** As established in k123935. Operating temperature is from 10-40°C with a relative humidity of 10-80%.
8. **Sample volume:** As established in k110017. The minimum sample volume is 0.7 µL.
9. **Readability:** A readability assessment was conducted and the results demonstrated that the User Manual, test strip package insert and control solution package insert were written at the 8th grade level.

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.