

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

A. 510(k) Number:

k123935

B. Purpose for Submission:

Modified device to include bluetooth wireless transmission technology, add LED display on the device, change memory capabilities, add internal power supply and minor modifications to the external appearance of the device. Control solution names have been modified.

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose oxidase

E. Applicant:

Andon Medical Co., Ltd.

F. Proprietary and Established Names:

iHealth BG5 Wireless Smart Gluco-Monitoring System
iHealth BG5L Wireless Smart Gluco-Monitoring System

G. Regulatory Information:

Device	Product Code	Classification	Regulation Section
iHealth BG5/5L Wireless Smart Gluco-Monitoring System	CGA, NBW (over the counter)	Class II	21 CFR § 862.1345, Glucose test system, over the counter, Glucose oxidase 21 CFR § 862.2100 Calculator/ Data Processing Module for Clinical Use
	JQP	Class I*	

	JJX	Class I, reserved	21 CFR § 862.1660, single (specified) analyte controls (assayed and unassayed)
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* A premarket notification (510 (k)) is required for the Class I devices meeting the limitations under 21CFR 862.9 (c)(5) For use in diabetes management

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

a. iHealth BG5 wireless Smart Gluco-Monitoring System

iHealth BG5 wireless Smart Gluco-Monitoring System is intended to be used for:

- quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf or thigh
- single person measurement only and should not be shared
- 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

iHealth BG5 wireless Smart Gluco-Monitoring System should not be used for the diagnosis of or screening for diabetes, or for neonatal use.

Alternative Site Testing (AST) should be done only during steady state times when glucose levels are not changing rapidly.

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

The iHealth control solutions are intended for use with the iHealth BG5 Blood Glucose Monitoring System, to check that the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

The iHealth Gluco-Smart App is an iOS app for iPhone, iTouch, and iPad and is used for data extraction and analysis in iHealth BG5 and BG5L Wireless Smart Gluco-Monitoring System.

b. iHealth BG5L wireless Smart Gluco-Monitoring System

iHealth BG5L wireless Smart Gluco-Monitoring System is intended to be used for:

- quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf or thigh
- single person measurement only and should not be shared
- 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

iHealth BG5L wireless Smart Gluco-Monitoring System should not be used for the diagnosis of or screening for diabetes, or for neonatal use.

Alternative Site Testing (AST) should be done only during steady state times when glucose levels are not changing rapidly.

The AGS1000I test strips are intended for use with the iHealth BG5 meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh using the iHealth BG5L meter.

The iHealth control solutions are intended for use with the iHealth BG5L Blood Glucose Monitoring System, to check that the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

The iHealth Gluco-Smart App is an iOS app for iPhone, iTouch, and iPad and is used for data extraction and analysis in iHealth BG5 and BG5L Wireless Smart Gluco-Monitoring System.

3. Special conditions for use statement(s):

- For over-the-counter use
- Not for neonatal use
- Not for screening or diagnosis of diabetes mellitus
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients
- For single-patient use only
- Alternative site testing (AST) testing should only be done during steady-state times (when glucose is not changing rapidly).
- AST should not be used to calibrate continuous glucose monitors (CGMs).
- AST should not be used for insulin dose calculations.

4. Special instrument requirements:

iHealth BG5 wireless Smart Blood Glucose Meter

iHealth BG5L wireless Smart Blood Glucose Meter

I. Device Description:

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 Wireless Smart Glucose meters are based on an electrochemical biosensor technology 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.

Control solutions (Level I, Level II, and Level III) are viscosity-adjusted, buffered aqueous control solutions that contain known concentrations of d-glucose. The products are intended for use to verify the performance of the The iHealth BG5 and BG5L Wireless Smart Glucose Monitoring Systems.

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.

J. Substantial Equivalence Information:

1. Predicate device name(s):
iHealth BG3 Smart Gluco-Monitoring System (Andon Medical Co., Ltd.)
2. Predicate 510(k) number(s):
k120813
k110017
3. Comparison with predicate:

CHARACTERISTICS	NEW DEVICE: iHealth BG5 and BG5L wireless Smart Gluco-Monitoring Systems	PREDICATE: iHealth BG3 Smart Gluco-Monitoring System(k120813)
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Indication for use	quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf or thigh; single person measurement only; self-testing outside the body by people with diabetes at home as an aid to monitor the effectiveness of diabetes control	The same
Detection Method	Amperometry	The same
Enzyme	Glucose Oxidase	The same
Type of Meter	Biosensor (Electrode)	The same
Sample Source	Capillary whole blood from AST(Alternative site testing) and finger	The same
Sample Application	Blood sample is placed directly to the test strip after finger or alternative site is lanced.	The same.
Hematocrit Range	20-60%	The same
Operating Temperature Range	50°-95°F (10°-35°C)	The same
Dimensions	9mm × 34.5mm × 19mm	102mm×58mm ×22mm
Display	LED display, Display on iPhone, iPod Touch or iPad connected through Bluetooth	Connect to iPhone or iPod touch to display measurement results
Result Presentation	mg/dL or mmol/L	The same
Memory Capabilities	500 times with time and date displaying	10000 times with time and date displaying
Test Start	Automatic	The same

Test Time	5 second	The same
Power Source	DC 3.7V d.c. li-ion 250mAh	DC 3.3V (Powered by iOS device)
Battery Life	N/A	N/A
Measurement Range	20mg/dL-600mg/dL (1.1mmol/L-33.3mmol/L)	The same
Qualified Test Strip	AGS-1000I Test Strip	The same
Sample Volume	Minimum 0.7 micro liter	The same
Other function	Transmit measure data to iPhone or iPod through blue tooth. iHealth BG5L uses Bluetooth 4.0 wireless radio technology; and iHealth BG5 uses Bluetooth 3.0 wireless radio technology	N/A

CHARACTERISTICS	NEW DEVICE: iHealth Control Solutions	PREDICATE: AG-608N Control Solutions(k110017)
Indication for use	Intended for use to verify the performance of the Glucose Monitoring Systems	Same
Number of Levels	Levels I, II and III	Same
Matrix	Viscosity-adjusted, buffered aqueous liquid	Same

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

- ISO 15197, In vitro diagnostic test systems- Requirements for in vitro whole blood glucose monitoring systems intended for use by patients for self testing in management of diabetes mellitus, First Edition 2003-05-01, Approved. (InVitro Diagnostics)
- IEC 61010-1: 2001, Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1:General requirements

- EN 61326-1:2006 Electrical equipment for measurement, control and laboratory use- EMC requirements part 1: General requirements
- EN 61326-2-6 Electrical equipment for measurement, control and laboratory use -EMC requirements Part 2-6: Particular requirements-In vitro diagnostic (IVD) medical equipment
- IEC 61010-2-101: 2002, Particular requirements for in vitro diagnostic (IVD) medical equipment
- CLSI EP6-A:2003, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

L. Test Principle:

The iHealth BG5 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:*

Within run (repeatability) and total (intermediate) precision was evaluated based on the ISO 15197 guideline.

The repeatability study was performed using heparinized anti- coagulated venous whole blood (hematocrit ranged from 35% to 50%) spiked to five different glucose concentrations (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL). Each sample was tested on ten meters using three lots of test strips. For each concentration, ten measurements were obtained per meter and test strip lot. (N=100 (10 meters x 10 measurements) per concentration level). Repeatability studies were performed on both BG5 and BG5L meters. The results are summarized below:

Repeatability of iHealth BG5 wireless Smart Gluco-Monitoring System

Concentration (mg/dL)	No. of Assay	Mean (mg/dL)	SD (mg/dL)	CV (%)	Hematocrit (%)
30-50	100	45.3	1.8	3.9	42.0%
51-110	100	92.9	2.6	2.8	41.6%
111-150	100	129.7	2.8	2.2	41.9%
151-250	100	213.7	5.4	2.5	41.2%
251-400	100	317.4	7.9	2.5	40.2%

Repeatability of iHealth BG5L wireless Smart Glucose Monitoring System

Concentration (mg/dL)	No. of Assay	Mean (mg/dL)	SD (mg/dL)	CV (%)	Hematocrit (%)
30-50	100	43.5	1.6	3.7	42.0%
51-110	100	92.5	2.4	2.6	41.6%
111-150	100	130.0	3.2	2.4	41.9%
151-250	100	213.4	5.2	2.5	41.2%
251-400	100	320.1	9.1	2.8	40.2%

Intermediate precision studies were performed using three levels of control solutions. iHealth control solutions control solutions, Level I, Level II and Level III, (45 mg/dL, 120 mg/dL and 320 mg/dL) were tested on ten meters using three lots of test strips (three meters with each of the three test strip lots) for ten days (N=100 per concentration level). Studies were performed on both BG5 and BG5L meters. The results are summarized below:

Intermediate precision of iHealth BG5 wireless Smart Gluco-Monitoring System

Control Solution Level	No. of Assays	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level I	100	47	1.7	3.6
Level II	100	103	3.3	3.2
Level III	100	361	8.8	2.5

Intermediate precision of iHealth BG5L wireless Smart Gluco-Monitoring System

Control Solution Level	No. of Assays	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level I	100	47	1.7	3.7
Level II	100	103	3.1	3.0
Level III	100	363	8.5	2.3

b. Linearity/assay reportable range:

Linearity study was designed based on CLSI EP6-A guideline.

Ten heparinized venous blood samples were spiked with dextrose covering the range from 20-600 mg/dL (hematocrit 45%), including 22, 32, 72, 124, 195, 284, 362, 459, 554, and 592 mg/dL. Glucose concentrations were confirmed by the YSI-2300. The study was performed using one calibrated meter and one vial of test on 5 replicates (N=36 per test strip lot). The only difference between the iHealth BG5 and BGL5 Wireless Smart meters is the version of wireless technology (BG5 uses 3.0 and BGL5

uses 4.0). Therefore, the linearity study was conducted on the iHealth BG5 wireless Smart Gluco-Monitoring System. The results are summarized below:

iHealth BG5 wireless Smart Gluco-Monitoring System:

Linearity/assay reportable range of iHealth BG5 wireless Smart Gluco- Monitoring System

Compared to YSI	Slope	Intercept	R ²
Linearity	0.9823	2.0611	0.9993

The claimed measuring range of the iHealth BG5 wireless Smart and iHealth BG5L wireless Smart Gluco-Monitoring Systems is 20 to 600 mg/dL.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability, stability and value assignment –

Traceability:

The system is traceable to the NIST SRM 917 glucose reference material. Traceability was evaluated in k120813.

Test Strip Stability:

The AGS-1000I blood glucose test strips are identical to the test strips in the predicate device, iHealth BG3 (k120813). Stability was evaluated in k120813.

Control Solution Stability:

The iHealth control solutions are identical to the test strips in the predicate device (k110017). Stability and value assignment were previously established in k110017.

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:

Previously established in k120813.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Previously established in k120813.

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):

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Expected blood glucose values for normal people without diabetes is cited from the literature and presented in the labeling as follows:

Fasting and before meal: <100 mg/dL

1-2 hours after meal: Less than 140 mg/dL

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

N. Instrument Name:

iHealth BG5 and BG5L wireless Smart Blood Glucose meters

O. System Descriptions:

1. Modes of Operation:

Using amperometry to detect glucose oxidase by biosensor (electrode)

2. Software:

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

this line of product types:

Yes or No

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

Yes or No

3. Specimen Identification:

Not applicable

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:

Not applicable

6. Quality Control:

The iHealth Control solution are used as a quality control checks to make sure that iHealth BG5/5L 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. Human factor (user performance) study. A human factors study was conducted with 30 enrolled participants. Participants received a dedicated meter and an iOS device and lancing device were recruited in the study.
 - a. Usability: One purpose of the human factor study was to verify that participants with average education and computer skills and no prior knowledge of the system can safely and accurately use the new device and the data transmission without direct instruction or training. Study results demonstrated that participants were able to transmit results from the meter to the iOS device via Bluetooth technology.
 - b. Readability: The participants were also asked to complete a questionnaire to evaluate the ease of use of the device and the clarity of the English language labeling. The readability of the labeling (user guides and test strip package insert) using a Flesch-Kincaid analysis were found to be written at the 8th grade level. Overall the users indicated that they could successfully perform the test and that the user manual was

written clearly.

2. IOS device data storage and memory roll over study: To assess the storage of the IOS device and the memory data rollover function, 10,000 data records were input into IOS device. The integrity of the stored data was confirmed by the data in BG5 glucose meters with 100% accuracy. The study demonstrated that the new data will replace the existed data orderly after the memory area room is full.
3. Electromagnetic Compatibility (EMC) testing was performed/ passed and a certificate was provided.
4. Hematocrit study. Evaluated in k120813.
5. Altitude Study. Evaluated in k120813.
6. Temperature and Relative Humidity Study. Evaluated in k120813.
7. Sample Volume Study. Evaluated in k120813.
8. Infection control: Candidate devices consist of same materials as the devices cleared under k110017. See k110017 for disinfection efficacy study information. Robustness studies were performed by the sponsor for this current submission demonstrating that there was no change in performance or external materials for each of the meters and lancing device after 11,000 cycles (each cycle contained pre-cleaning and disinfection steps) with the CaviWipes. The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

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.