

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

A. 510(k) Number:

k120813

B. Purpose for Submission:

Modification to cleared meter to connect and provide User Interface with iOS iPhone and iPod

C. Measurand:

Capillary Whole Blood Glucose

D. Type of Test:

Quantitative, electrochemical biosensor, glucose oxidase

E. Applicant:

ANDON MEDICAL CO., LTD

F. Proprietary and Established Names:

iHealth BG3 Smart Gluco-Monitoring System

G. Regulatory Information:

1. Regulation section:

21CFR Sec.-862.1345 Glucose test system.

21CFR Sec.-862.1660 Quality control material (assayed and unassayed).

21CFR Sec.-862.2100 Calculator/data processing module for clinical use.

2. Product code:

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

CGA - Glucose Oxidase

JQP - calculator/data processing module, for clinical use

3. Classification:

Class 2

Class 1, subject to limitations 21CFR862.9(c)(5) respectively

4. Panel:
Clinical Chemistry (75)

H. Intended Use:

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

2. Indication(s) for use:

iHealth BG3 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

The iHealth BG3 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 BG3 meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh using the iHealthBG3 meter.

3. Special conditions for use statement(s):

- For in vitro diagnostic use only
- For over-the-counter use
- For single-patient use only
- Not intended for use on neonates
- Not for the diagnosis of or screening for diabetes mellitus
- Not for use on patients who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.
- Not for use in critically ill patients
- AST results should not be used to calibrate a continuous glucose monitor (CGM) or in insulin dose calculations

4. Special instrument requirements
iHealth BG3 Meter

I. Device Description:

iHealth BG3 Smart Gluco-Monitoring System consist of blood glucose meter, test strips, sterile lancets, lancing device and AGS1000I Control Solutions (Level I, Level II and Level III) cleared under k110017.

The device iHealth BG3 Smart Gluco-Monitoring System is 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, , is used to test the performance of the device.

The appearance of the subject iHealth BG3 Smart Gluco-Monitoring System is different from the predicate device. The subject device iHealth BG3 Smart Gluco-Monitoring System must connect to an iPhone or iPod touch to display the results and complete its function.

J. Substantial Equivalence Information:

1. Predicate device name(s):
AG-608N Single Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
K110017

3. Comparison with predicate:

CHARACTERISTICS	SUBJECT DEVICE: iHealth BG3 Smart Gluco-Monitoring System	PREDICATE: AG-608N Single Blood Glucose Monitoring System (K110017)
Indications for use	<p>iHealth BG3 Smart Gluco-Monitoring System is intended to be used for:</p> <ul style="list-style-type: none"> • 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 <p>The iHealth BG3 Smart Gluco-Monitoring System should not be used for the diagnosis of or screening for diabetes, or for neonatal use.</p> <p>Alternative Site Testing (AST) should be done only during steady state times when glucose levels are not changing rapidly.</p> <p>The AGS1000I test strips are intended for use with the iHealth BG3 meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh using the iHealthBG3 meter.</p>	Same

Detection Method	Amperometry	Same
Enzyme	Glucose Oxidase	Same
Type of Meter	Biosensor (Electrode)	Same
Sample Source	Capillary whole blood from finger, palm, forearm, upper arm, calf and thigh	Same
Sample Application	Blood sample is placed directly on the test strip after finger or AST is lanced.	Same
Hematocrit Range	20-60%	Same
Operating Temperature Range	10°C~35°C (50°-95°F)	10°C ~40°C (50°-104°F)
Dimensions	102mm×58mm ×22mm	52mm x 92mmx
Display	Connect to iPhone or iPod touch to display measurement results	LCD
Result Presentation	mg/dL or mmol/L	Same
Memory Capabilities	10000 times with time and date displaying	500 times with time and
Test Start	Automatic	Same
Test Time	5 second	Same
Power Source	DC 3.3V (Powered by iOS device connected to the meter)	DC 3V (CR2032)
Battery Life	N/A	Approx. 500
Measurement Range	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)	Same
Qualified Test Strip	AGS-1000I Test Strip	AGS-1000N Test
Sample Volume	Minimum 0.7 micro liter	Same

Other function	N/A	USB function. Voice function
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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. (In Vitro Diagnostics)

IEC 61010-1, Safety requirements for electrical equipment for measurement, control, and laboratory use, 2001

EN 61326:2006 Electrical equipment for measurement, control and laboratory use

L. Test Principle:

The test is based on electrochemical biosensor technology and the principle of capillary action. The electrical current generated by the reaction of glucose with the reagent of the strip is measured by the meter and is displayed on an iPhone or iPod touch as the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

M. Performance Characteristics (if/when applicable):

The device is a modification of a cleared AG-608N meter (k110017) to connect and provide the User Interface with iOS iPhone and iPod using the same test strip and control cleared with the AG-608N meter in k110017. 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

- d. *Detection limit:*
As established in k110017
 - e. *Analytical specificity:*
As established in k110017
 - f. *Assay cut-off:*
As established in k110017
2. Comparison studies:
- a. *Method comparison with predicate device:*
As established in k110017
 - b. *Matrix comparison:*
As established in k110017
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 consumer study in k110017 to test the effects of 100 lay-users on the performance of their candidate device. The results of this testing are described in k110017.

The performance established in k110017 was confirmed with Consumer Accuracy data derived from the Human Factors (HF) study described in section P of this document. The results* using 30 meters and iPhones are described below:

System Accuracy Results comparing meter finger results to YSI

Glucose concentrations < 75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
4/6	6/6	6/6
67%	100%	100%

Glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
10/24	19/24	23/24	24/24
42%	79%	96%	100%

* Note: HF studies were conducted on 60 systems (30 iPhones and 30 iPods), however, only the 30 iPhones were evaluated for data accuracy. The data tables above reflect the performance data generated from the 30 iPhones.

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

(1) American Diabetes Association: Diagnosis and Classification of Diabetes Mellitus (Position Statement). Diabetes Care 34 (Supp. 1) S66, 2011.

(2) Tietz Fundamentals of Clinical Chemistry, 6th Edition, Edited by Burtis CA and Ashwood ED, W. B. Saunders Co., Philadelphia, PA, 2008, p. 849.

N. Instrument Name:

iHealth BG3 Meter

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 or No

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

Yes or No

2. Software:

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

Yes or No

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:

This device is intended to be used with capillary whole blood from the finger and other alternative sites (palm, forearm, upper-arm, calf and thigh). Since the whole blood sample is applied directly to the test strip, there are no special handling or storage issues.

5. Calibration:

Auto-coding: No calibration is required from the user, since all test strips have the same one-code.

6. Quality Control:

No quality control (QC) tracking software is provided. The user is advised to monitor QC material when testing is within labeled range. Three levels of

aqueous glucose control solutions are available with this system. Control solution Level 2 is provided with the kit. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

Applicable temperature and humidity studies; sample volume study; Altitude study; hematocrit study were established in k110017

1. A readability assessment was conducted by SMOG method on the instructions for use, and they were found to be at 8th grade reading level or below.
2. Human Factors testing
A human factors study was conducted with 30 lay user participants, using 30 iPhones, 30 iPod Touch devices, 60 iHealth BG3 meters (30 will dock iPhone and 30 will dock iPod Touch) and 3 lots of test strips. As part of the human factors study, the 30 lay user participants used their own fingersticks to evaluate data accuracy to the 30 iPhones, as described in section M.3.c. above. The study participants had varied, but not advanced computer skills. The first 10 users used test strip lot 1, the second 10 users used test strip lot 2, and the last 10 users used test strip lot 3. The users were given labeling in English and instructed to set up and use the system as intended to be used. Results of this study are described in section M.3.c above.

Lay user questionnaire: Lay users evaluated the ease of use of the device and the presentation of the labeling. All users thought that the iHealth BG3 Smart Gluco-Monitoring System was easy to use and most answered “easy” and “very easy” to each question.

3. Bench testing performed for data from meter to iPhone or iPod device
Bench testing was performed to verify the transmission accuracy of electrical signals between Apple's mobile operating system for iPhone and iPod platforms (iOS) and glucose meter. This evaluation consisted of the following: sending of data (output from the glucose meter) and receiving of data (input

into the iOS device). Data from the glucose meter and the receiving data on iOS device, was in 100% agreement

4. Bench testing memory limits and rollover synchronization.
Testing was performed to evaluate that the iOS and device can save 10000 records and that the records can rollover properly in the iOS app. The criteria for successful rollover of data were that when the memory is full, the new record will replace the record that existed from the first record. The stated acceptance criteria was met for this study
5. Electromagnetic Compatibility (EMC) testing was performed/ passed. A certificate verifying that EMC testing was performed and passed was provided.
6. The applicant provided software documentation and testing that supports the device was developed and is under good software lifecycle processed.
7. Disinfection studies/Infection Control Studies: The devices are intended for single-patient use (iHealth BG3 Smart Gluco-Monitoring System). Disinfection efficacy studies were performed on the materials comprising the meters and lancing device by outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, CaviWipes (EPA Registration #46781-8). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials for each of the meters and lancing device after 11,000 cleanings and 11,000 disinfection steps with the CaviWipes. The robustness studies were designed to stimulate 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 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.

8. Customer service is available Monday through Friday 8:30 am to 5:30 pm Pacific Standard Time at the following toll-free number: 1-855-816-7705. The labeling instructs patients to contact their healthcare provider at all other times for help)

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.