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

A. 510(k) Number:

k181070

B. Purpose for Submission:

Modifications to a previously cleared device including: an update to the Bluetooth module, narrowing the measuring range, removing a cleared test strip chemistry, and adding compatible 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 dehydrogenase (GDH-FAD)

E. Applicant:

Andon Health Co., Ltd.

F. Proprietary and Established Names:

iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345, Glucose test system

2. Classification:

   Class II

3. Product code:

   NBW, System Test, Blood Glucose, Over the Counter

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) consists of the iHealth Wireless Smart Glucose Meter (BG5S) and the iHealth Blood Glucose Test Strips (EGS-2003). The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) 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 Smart Gluco-Monitoring System (iHealth Gluco+) is intended to be used by a single person and should not be shared.

   iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) 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 Smart Gluco-Monitoring System (iHealth Gluco+) 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):

   - The iHealth system is not intended for use on neonates or for the screening or diagnosis of diabetes.
   - For over-the-counter use
   - For single-patient use
   - Patients undergoing oxygen therapy may yield falsely lower results.
   - The meter and lancing device are for single patient use.
   - Not for use on critically ill patients.
   - This device is not for use on people who are severely dehydrated, on people who are severely hypotensive, or people who are in shock.
   - Use only fresh capillary whole blood samples to test your blood glucose.
   - 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 self-testing only.
   - Do not perform alternate site testing (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, of ir your routine glucose results fluctuate

often.

- Do not use AST results to calibrate a continuous glucose monitor (CGM) or for insulin dosing calculations.
- AST should only be used during times when blood sugar is not fluctuating rapidly, (i.e. within 2 hours of eating, exercising or taking medication).

4. Special instrument requirements:

   iHealth Wireless Smart Glucose Meter (BG5S)

I. Device Description:

The iHealth Wireless Smart Gluco-Monitoring System(iHealth Gluco+) consists of the iHealth Wireless Smart Meter (BG5S) and the iHealth Blood Glucose Test Strips (EGS-2003). The iHealth BG5S Meter displays the test results and the test results can also be transmitted wirelessly to a compatible mobile device using the iHealth Gluco+ App. When used with this meter, the iHealth Gluco+ App is used to identify a control solution test in the meter memory. The App can transfer data from the device's memory, manage, and share the data.

The iHealth Glucose Control Solutions Level I, Level II, and Level III were previously cleared in k123935.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   iHealth Wireless Smart Gluco-Monitoring System (BG5)

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

   k170231

3. Comparison with predicate:

Similarities/Differences		
Item	Candidate Device (k181070)	Predicate Device (k170231)
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

Similarities/Differences		
Item	Candidate Device (k181070)	Predicate Device (k170231)
Detection method	Amperometry	Same
Sample source	Capillary whole blood from AST (alternative site testing) and finger	Same
Test strip chemistry(ies) cleared for use with meter	Glucose dehydrogenase (EGS-2003)	Glucose oxidase (AGS-1000I) and glucose dehydrogenase (EGS-2003)
Display	White LED color	Blue LED color
Measurement range	50-600 mg/dL	20-600 mg/dL
Bluetooth	Bluetooth 4.0	Bluetooth 3.0
Compatable mobile platforms/operating systems	Addition of iPhone models (7Plus, 8, 8Plus, X) and Samsung models (Galaxy S8, Galaxy Note 8) Operating Systyem: up to iOS 12.0 and Android 9.0	iPhone (4S, 5, 5C, 5S, 6, 6S, 6Plus, 6sPlus), iPad (3, 4, mini, air, mini 2, air 2, mini 3) iPod (touch 5), Samsung (Galaxy S3, S4, S5, S6, S6 Edge, S7, S7 Edge, Note2, Note3), HCT One M7, LG Nexus (4, 5) and Motorola Nexus Operating System: up to iOS 10.0 and Android 7.0

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

IEC 61010-1:2010, Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements.

IEC 60601-1-2:2014, Medical Electrical Equipment, Part 1-2: General Requirements For Basic Safety And Essential Performance.

L. Test Principle:

The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) measures glucose amperometrically. The reaction of glucose dehydrogenase and an electron mediator in the EGS-2003 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 and the iHealth Gluco+ mobile App.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Established in k170231 and not impacted by the modifications.

b. Linearity/assay reportable range:

Linearity was evaluated using eleven venous whole blood samples with glucose concentrations of 51.1, 64.9, 85.9, 120.3, 150.5, 170.8, 225.5, 279.5, 328.3, 488.8, and 595.5 mg/dL as measured by the comparator method, YSI 2300. Each sample was tested with 9 BG5S meters for 9 measurements per glucose concentration. The linear regression results are presented below:

$y = 0.9845x + 0.749$; $R2=0.9954$

The results of the linearity study support the sponsor's claimed glucose measurement range of 50-600 mg/dL. If a sample is less than 50 mg/dL or greater than 600 mg/dL an error message is returned to the user. The error messages were validated using blood glucose samples outside the measuring range of the device and demonstrated that the error messages function as intended.

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

The system is traceable to NIST SRM #917c reference material and calibrated to be plasma-equivalent.

Stability (open- and close-vial) of the EGS-2003 test strips were evaluated in k170231 and support the claimed shelf life of 24 months when stored at 39 to 86ºF (4-30ºC) with relative humidity of 10-85% and 5 month stability after opening when stored at the same conditions.

d. Detection limit:

See linearity study in M.1.b above.

e. Analytical specificity:

Potential interference from common endogenous and exogenous substances was evaluated in k170231 and not impacted by the modifications. Based on this testing, the labeling includes the following limitations:

- If you take acetaminophen or acetaminophen containing medications (Tylenol, certain cold and flu remedies, or certain prescription drugs) this

medication might affect the reliability of your blood glucose results (blood concentrations >5 mg/dL). If you are unsure, then ask your healthcare professional.

- Certain conditions may cause your blood level of uric acid to rise. These conditions include gout or kidney disease. 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 you are unsure, then ask your healthcare professional.
- Vitamin C (Ascorbic acid (>4 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.
- Do not use this device during or shortly after receiving xylose absorption therapy since xylose may cause inaccurate blood glucose results.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

See M.3.c. below.

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):

Accuracy in the hands of the intended user was established in k170231, however, the sponsor performed a supplemental usability study to demonstrate whether the minor modifications to the predicate device (BG5 meter, k170231) that resulted in the candidate device (BG5S meter) impacted usability. The lay users (341 subjects) were provided the BG5S meter with a test strip vial (EGS-2003 test strips) and labeling. Approximately half of the users were provided a iPhone 6S mobile device while the other half were provided a Samsung Galaxy S7 Edge mobile device. These mobile

devices were selected as representative mobile devices based on the user interface as well as hardware and software functionalities The lay users performed their own finger stick and blood glucose test, followed by a trained technician obtaining a sample for testing on the comparator method, YSI 2300. The study participants were asked to complete a usability questionnaire regarding ease of understanding of information in the user manual and the ease of use when performing a blood glucose test. The study demonstrated that users of the device were able to understand and follow the instructions provided in the labeling to perform tasks involved in blood glucose testing.

4. Clinical cut-off:

   Not applicable.

5. Expected values/Reference range:

   The following expected values for people without diabetes are provided 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. (Standards of Medical Care in Diabetes – 2018. Diabetes Care, January 2018, vol. 41, Supplement 1, S13-S27).

N. Instrument Name:

iHealth Wireless Smart Glucose Meter (BG5S)

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:

   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 fresh 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:

   The meter does not require calibration or coding by the user.

6. Quality Control:

   Three levels of aqueous glucose control solutions are available with this system (iHealth Glucose Control level 1, level 2, level 3). Level II control is included in the kit and Level I and III may be purchased separately.

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

1. Hematocrit:
   Established in k170231 to support the claimed hematocrit range of 20-60% and not impacted by the modifications.

2. Altitude:
   Established in k170231 to support the use of the device up to 10,744 ft. (3275 meters) and not impacted by the modifications.

3. Operating Conditions:
   Established in k170231 to support the claimed operating condition range of 41°F -104°F (10°C~40°C) and 25%-80% relative humidity and not impacted by the modifications.

4. Infection Control:
   The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) is intended for single-patient use. Disinfection efficacy was established in k110017, demonstrating complete inactivation of hepatitis B (HBV) virus using materials comprising the meter and CaviWipes Disinfecting Towelettes (EPA registration #46781-8). Robustness testing was performed demonstrating that there was no change in performance or in the external

materials of the meters 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. Sample Volume:
   Established in k170231 to support a 0.7 µL sample volume and not impacted by the modifications.

6. EMC and Electrical Safety:
   The sponsor provided documentation certifying that acceptable electromagnetic testing (EMC) had been performed.

7. Test Strip Lot Release Protocol:
   The test strip lot release protocol and criteria were reviewed and found to be acceptable.

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.