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

A. 510(k) Number:

k170231

B. Purpose for Submission:

Adding new test strips (EGS-2003) for use with the iHealth Align Glucose meter (BG1) and the iHealth Wireless Glucose meter (BG5) to replace the tests strips previously cleared with these meters

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

E. Applicant:

Andon Health Co., Ltd.

F. Proprietary and Established Names:

iHealth Align Gluco-Monitoring System (BG1)
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

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

The iHealth Align Gluco-Monitoring System (BG1) consists of the iHealth Align Glucose meter (BG1), iHealth Blood Glucose Test Strips (EGS-2003), 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 (BG1) 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).

The iHealth Wireless Smart Gluco-Monitoring System (BG5) consists of the iHealth Wireless Glucose meter (BG5), iHealth Blood Glucose Test Strips (EGS-2003), and the iHealth Gluco-Smart App mobile application. The iHealth Wireless Smart 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 Smart Gluco-Monitoring System (BG5) 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 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 following apply to both systems:

- For over-the-counter use.
- Not to be used for the diagnosis of or screening of diabetes or for neonatal use.
- Not intended for use on arterial or venous whole blood, serum or plasma.
- Patients undergoing oxygen therapy may show results lower than actual levels.
- Not for use on critically ill patients.
- Use only fresh capillary whole blood samples to test your blood glucose.
- These device is not for use in people who are severely dehydrated, in people who are severely hypotensive, or people who are in shock. Test results that are

lower than actual values may occur in individuals who are in a hyperglycemic-hyperosmolar state, with or without ketosis.
- 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.
- For single-patient use only.
- 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 intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

4. Special instrument requirements:

   iHealth Align Glucose meter (BG1)
   iHealth Wireless Glucose meter (BG5)

I. Device Description:

iHealth Align Gluco-Monitoring System (BG1)

The iHealth Align Gluco-Monitoring System (BG1) consists of the iHealth Align Glucose meter (BG1) (referred to as 'BG1 meter'), iHealth Blood Glucose Test Strips, EGS-2003 sterile lancets, lancing device, iHealth glucose control solutions, and sanitary covers for the mobile devices. The BG1 meter must be used with a compatible mobile device (iOS version 8.0/9.0/10.0 or Android 4.2/5.0/6.0/7.0). A mobile app (iHealth Gluco-Smart App) installed on the mobile device serves as the only 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. The list of compatible mobile devices is provided in the product labeling.

iHealth Wireless Smart Gluco-Monitoring System (BG5)

The iHealth Wireless Smart Gluco-Monitoring System (BG5) consists of the iHealth Wireless Smart blood glucose meter (BG5) (also referred to as 'BG5 meter), the iHealth Blood Glucose Test Strips, EGS-2003 test strips, sterile lancets, lancing device and the iHealth glucose control solutions. The iHealth BG5 meter can display the test results and the test results can also be transmitted wirelessly to an Apple (iOS version 8.0/9.0/10.0) or Android (4.2/5.0/6.0/7.0) based mobile device using the iHealth Gluco-Smart App. 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. The list of compatible mobile devices is provided in the product labeling.

Both BG1 and BG5 meters have previously been cleared for use with glucose oxidase based test strip chemistry, the AGS 1000I Test Strips. The current systems are for use with glucose dehydrogenase based chemistry, the iHealth Blood Glucose Test Strips, EGS-2003 that will replace the AGS 1000I Test Strips on the market for use with both meters.

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 Align Gluco-Monitoring System (BG1)
   iHealth Wireless Smart Gluco-Monitoring System (BG5)

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

   k153278

3. Comparison with predicate:

Similarities			
	Predicate Device (k153278)	Candidate Device (k170231)	
Item	iHealth Align Gluco-Monitoring System (BG1)	iHealth Align Gluco-Monitoring System (BG1)	iHealth Wireless Smart Gluco-Monitoring System (BG5)
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	Same
Test Principle	Amperometry	Same	Same
Hematocrit	20-60%	Same	Same
Measuring	20-600 mg/dL	Same	Same
Sample Volume	0.7 µL	Same	Same
Test Time	5 seconds	Same	Same

Similarities			
	Predicate Device (k153278)	Candidate Device (k170231)	
Item	iHealth Align Gluco-Monitoring System (BG1)	iHealth Align Gluco-Monitoring System (BG1)	iHealth Wireless Smart Gluco-Monitoring System (BG5)
Control Solutions	iHealth Glucose Control Solutions (Level I, Level II and Level III)	Same	Same
Altitude	10744 ft	Same	Same
Operating Temperature	50-104ºF	Same	Same
Alternative Site Testing	Palm, forearm, upper arm, calf, or thigh	Same	Same

Differences			
Item	**Predicate Device** (k153278)	**Candidate Device** (k170231)	
	iHealth Align Gluco-Monitoring System	iHealth Align Gluco-Monitoring System (BG1)	iHealth Align Gluco-Monitoring System (BG5)
Test Strip	AGS-1000I Test Strip	EGS-2003 Test Strip	EGS-2003 Test Strip
Coding	QR-code	No-coding	No-coding
Strip chemistry	Glucose oxidase	Glucose Dehydrogenase	Glucose Dehydrogenase
Compatible OS version	iOS 7.0, 8.0, 9.0 Android 4.0, 4.2, 4.4, 5.0	iOS version 8.0,9.0,10.0 Android 4.2,5.0,6.0,7.0	iOS version 8.0,9.0,10.0 Android 4.2,5.0,6.0,7.0)

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) and iHealth Wireless Smart Gluco-Monitoring System (BG5) 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 mobile app.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Repeatability was evaluated using ten BG1 and ten BG5 meters and three lots of EGS-2003 test strips. Venous whole blood samples adjusted to five glucose concentrations of (30-50, 51-110,111-150, 151-250, and 251-400 mg/dL) were tested in replicates of ten with each meter and strip lot combination resulting in 300 measurements per glucose level. Results are summarized below for each of the test strip lots:

BG1 meter with the EGS-2003 test strip:
Strip Lot 1:

Concentration (mg/dL)	No. of Assay	Average (mg/dL)	SD (mg/dL)	CV (%)
30-50	100	48.7	2.8	5.6
51-110	100	95.1	3.5	3.7
111-150	100	114.1	4.4	3.8
151-250	100	177.4	7.4	4.1
251-400	100	304.2	10.2	3.4

Strip Lot 2:

Concentration (mg/dL)	No. of Assay	Average (mg/dL)	SD (mg/dL)	CV (%)
30-50	100	47.8	2.9	6.2
51-110	100	99.6	4.6	4.6
111-150	100	129.8	6.0	4.6
151-250	100	179.9	6.2	3.4
251-400	100	307.9	12.3	4.0

Strip Lot 3:

Concentration (mg/dL)	No. of Assay	Average (mg/dL)	SD (mg/dL)	CV (%)
30-50	100	44.1	2.9	6.7
51-110	100	94.4	3.8	4.0
111-150	100	127.6	5.1	4.0
151-250	100	184.5	8.0	4.3
251-400	100	307.0	13.3	4.3

BG5 meter with the EGS-2003 test strip:
Strip Lot 1:

Concentration (mg/dL)	No. of Assay	Average (mg/dL)	SD (mg/dL)	CV (%)
30-50	100	46.9	1.9	4.1
51-110	100	100.5	3.3	3.3
111-150	100	128.2	5.5	4.3
151-250	100	183.2	5.7	3.1
251-400	100	371.7	16.1	4.3

Strip Lot 2:

Concentration (mg/dL)	No. of Assay	Average (mg/dL)	SD (mg/dL)	CV (%)
30-50	100	47.3	2.1	4.3
51-110	100	98.3	3.5	3.5
111-150	100	126.3	5.7	4.5
151-250	100	177.8	6.7	3.7
251-400	100	360.2	12.6	3.5

Strip Lot 3:

Concentration (mg/dL)	No. of Assay	Average (mg/dL)	SD (mg/dL)	CV (%)
30-50	100	49.4	2.3	4.6
51-110	100	93.2	3.5	3.8
111-150	100	124.9	4.5	3.6
151-250	100	172.3	6.6	3.8
251-400	100	358.6	12.6	3.5

Intermediate precision was evaluated using three levels of control solutions with concentration ranges of 30-50, 111-150, and 251-400 mg/dL. Each sample was

measured once per day using ten BG1or BG5 meters and three EGS-2003 test strip lots, over 10 days for a total of 300 tests per glucose level. Results from the test strip lots are combined and summarized below:

BG1 meter with the EGS-2003 test strip:

Control Solution	No. of Assays	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level I	300	47.3	3.7	7.8
Level II	300	111.0	5.2	4.7
Level III	300	332.8	16.4	4.9

BG5 meter with the EGS-2003 test strip:

Control Solution	No. of Assays	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level I	300	44.9	3.5	7.7
Level II	300	133.0	5.3	4.0
Level III	300	383.7	15.6	4.1

b. Linearity/assay reportable range:

Linearity was established using nine spiked venous whole blood samples with Glucose concentrations of 22.2, 38.1, 63.6, 98.2, 172, 236, 356, 422, and 598 mg/dL as measured on the comparator method, YSI.

Each sample was tested in 5 replicates using EGS-2003 test strips and BG1 or BG5 meters. The liner regression results are presented below:

BG1: $y = 0.9761X-3.8574$; $R^2=0.9989$
BG5: $y = 0.9665x+3.8313$; $R^2=0.9984$

The results of the linearity study support the sponsor's claimed glucose measurement range of 20-600 mg/dL for both systems. If a sample is less than 20 mg/dL, the result is flagged by the meters as LO. If a sample result exceeds 600 mg/dL, the result is flagged by the meters as HI. The Hi and Lo features were validated using blood glucose samples outside the measuring range of the device and demonstrated that the features function as intended.

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

Traceability:
The system is traceable to NIST SRM #917c reference material and calibrated to be

plasma-equivalent.

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 supports 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 Section M1b above.

e. Analytical specificity:

The sponsor performed interference studies using the iHealth Align Gluco-Monitoring System (BG1) to support the use of the EGS-2003 test strips with both the BG1 and BG5 meters. Spiked venous blood samples at two glucose concentrations of 60 and 350 mg/dL were divided into a test pool and a control pool. The potential interfering substances were added to the test sample at low and high concentrations. Each sample was measured in 5 replicates using the BG1 meter and EGS-2003 test strips. The differences between meter results between the test sample and the control sample were calculated. The table below lists the highest concentration at which no significant interference (<10%, as defined by the sponsor) was observed for the substances tested.

Chemical Compound	**Highest concentrations without significant interference (mg/dL)**
Acetaminophen	5
Ascorbic acid	4
Bilirubin	40
Cholesterol	700
Creatinine	5
Dopamine	0.09
Galactose	15.1
Gentisic acid	117
Glutathione	28
Hemoglobin	450

Chemical Compound	Highest concentrations without significant interference (mg/dL)
Heparin	3000U/L
Ibuprofen	50
Icodextrin	7.5
L- Dopa	1.35
Maltose	500
Methyl dopa	1.5
Pralidoxime lodide	55.5
Salicylate	60
Tolbutamide	64
Tolazamide	30
Triglycerides	200
Uric acid	10
Xylose	45

The following limitations for use are included in the labeling for the test strip:

- If you are taking acetaminophen containing drugs (Tylenol and other medicines containing acetaminophen, blood concentrations >5 mg/dL) or Vitamin C (ascorbic acid, blood concentrations >4 mg/dL) at doses higher than recommended, these may interfere with your glucose meter and cause you to get inaccurate results with this system.
- 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.
- 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:*

      Not applicable.

   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):*

      The sponsor performed 2 separate lay user performance studies using 350 subjects in each study testing BG1 and BG5 blood glucose monitoring system, respectively. The lay user was provided a BG1 or BG5 meter with a test strip vial, labeling, and a smart phone (iPhone 6S or Samsung Galaxy S6 Edge). The lay users performed their own finger stick test and testing from alternative sites (palm, forearm, upper arm, calf, thigh), followed by a trained technician obtaining a capillary sample for testing on the comparator method, YSI. The results of the first measurement obtained by each participant are summarized in the tables below.

      BG1 meter with the EGS-2003 test strip:

      Glucose Concentrations ≤ 75 mg/dL

Sample Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger stick	33/53 (62.3%)	51/53 (100%)	53/53 (100%)
Palm	34/54 (63.0%)	54/54 (100%)	54/54 (100%)
Forearm	28/55 (50.9%)	55/55 (100%)	55/55 (100%)

Sample Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Upper arm	35/54 (64.8%)	54/54 (100%)	54/54 (100%)
Calf	34/51 (66.7%)	51/51 (100%)	51/51 (100%)
Thigh	36/54 (66.7%)	53/54 (98.1%)	54/54 (100%)

Glucose Concentrations >75 mg/dL

Sample site	Within 5%	Within 10%	Within 15%	Within 20%
Finger stick	131 /297 (44.1%)	239 /297 （80.5%）	289 /297 （97.3%）	297 /297 （100%）
Palm	132/296 (44.6%)	245/2968 (82.8%)	287/296 (97.0%)	296/296 (100%)
Forearm	132/295 (44.7%)	239/295 (81.0%)	287/295 (97.3%)	295/295 (100%)
Upper arm	124/296 (41.9%)	244/296 (82.4%)	292/296 (98.6%)	296/296 (100%)
Calf	127/299 (42.5%)	249/299 (83.3%)	292/299 (97.7%)	299/299 (100%)
Thigh	127/296 (42.9%)	231/296 (78.0%)	289/296 (97.6%)	296/296 (100%)

Liner regression between BG1 meter with the EGS-2003 test strip and YSI:

	Finger	Palm	Forearm	Upperarm	Calf	Thigh
Slope	0.9896	0.9733	1.0139	0.9825	0.9975	1.0000
Y-Intercept	-0.8661	1.0008	-4.2613	0.0885	-2.3566	-3.3990
R^2	0.9843	0.9832	0.9841	0.9827	0.9838	0.9837

BG5 meter with the EGS-2003 test strip:

Glucose Concentrations ≤75 mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger	38/58 (65.5%)	56/58 (96.6%)	58/58 (100%)
Palm	37/57 (64.9%)	56/57 (98.2%)	57/57 (100%)
Forearm	35/56 (62.5%)	55/56 (100%)	56/56 (100%)
Upper arm	40/57 (70.2%)	56/57 (98.2%)	57/57 (100%)
Calf	39/56 (69.6%)	55/56 (98.2%)	56/56 (100%)
Thigh	42/57 (73.7%)	57/57 (100%)	57/57 (100%)

Glucose Concentrations >75 mg/dL

	Within ± 5 %	Within ± 10 %	Within ± 15%	Within ± 20%
Finger	130/292 (44.5%)	240/292 (82.2%)	286/292 (97.9%)	292/292 (100%)
Palm	132/293 (45.1%)	248/293 (84.6%)	285/293 (97.3%)	293/293 (100%)
Forearm	129/294 (43.9%)	250/294 (85.0%)	290/294 (98.6%)	294/294 (100%)
Upper arm	123/293 (42.0%)	245/293 (83.6%)	288/293 (98.3%)	293/293 (100%)
Calf	124/294 (42.2%)	250/294 (85.0%)	287/294 (97.6%)	294/294 (100%)
Thigh	125/293 (42.7%)	240/293 (81.9%)	286/293 (97.6%)	293/293 (100%)

Liner regression between BG1 meter with the EGS-2003 test strip and YSI:

	Finger	Palm	Forearm	Upper arm	Calf	Thigh
Slope	0.9884	0.9732	1.0134	0.9873	0.9962	0.9978
Y-Intercept	-0.5586	1.1092	-4.1086	-0.5178	-2.0323	-3.0252
R^2	0.9848	0.9838	0.9846	0.9840	0.9839	0.9843

Usability Questionnaire results demonstrated that the device was easy to use and the instructional materials were easy to read and understand for both systems. A readability evaluation was conducted for the BG5 and BG1 user manuals and the EGS-2003 test strip insert. The grade level was determined to be at the 8th grade level for all the labeling.

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)
iHealth Wireless Smart Glucose Meter (BG5)

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and must be replaced with a new strip for additional readings.

   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?

   BG1: Yes _____ or No ___X____

   BG5: 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 _____

   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 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:

   When using the EGS-2003 test strip, no coding is necessary by the user when using either the BG1 or BG5 meters.

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. 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: The effect of different hematocrit levels on the iHealth Align Gluco-Monitoring System (BG1) and the iHealth Wireless Smart Gluco-Monitoring System (BG5) was evaluated using venous whole blood samples with hematocrit levels of 20 – 60% (20%, 30%, 42%, 50%, 60%) at glucose to concentrations of 40, 110 and 300 mg/dL. Results of samples at each hematocrit level were compared to samples with the same glucose concentration at normal (42%) hematocrit as well as to the corresponding YSI value. The % bias of the meter results relative to YSI demonstrated adequate performance to support the claimed hematocrit range of 20 – 60%.

2. Altitude study: Effect of altitude was evaluated using 10 BG1 meters and 10 BG5 meters, respectively and six venous blood (spiked and glycolyzed) samples from 2 donors at six glucose concentrations (49, 60, 96, 104, 278, 288 mg/dL). The samples were tested under conditions to simulate 10744 feet above sea level and sea level (0 feet) as a control. Results obtained were compared with those obtained with the reference method (YSI). The results demonstrated acceptable bias to the reference to support the claims in the labeling that

altitudes up to 10,744 feet have no significant effect on blood glucose measurements from the iHealth Align Gluco-Monitoring System (BG1) and the iHealth Wireless Smart Gluco-Monitoring System (BG5).

3. Operating Temperature and Humidity: Temperature and humidity operating conditions were evaluated for temperatures ranging from 41°F-104°F (10°C~40°C), and relative humidity (RH) from 25%~80% including extreme combinations of temperature and humidity, e.g. lowest humidity with lowest and highest temperature and highest humidity with lowest and highest temperature. Protocol and acceptance criteria were provided and found to be acceptable. The results supported the Sponsor's claimed operating temperature from 41°F-104°F and relative humidity range from 25% to 80% for both BG1 and BG5 meters.

4. Infection Control Study:
   The iHealth Align Gluco-Monitoring System (BG1) and iHealth Wireless Smart Gluco-Monitoring System (BG5) is intended for single-patient use. Disinfection efficacy for the BG1 and BG5 meters was established in k123935 and k110017, respectively, 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. 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 (BG1).

5. Sample volume requirements: The minimum sample volume is 0.7 µL. The sponsor performed a study to verify the test strip sample volume requirement and the test strip fill error requirement established using BG5 Blood Glucose Meter. Blood samples were tested at 4 sample volumes (0.4, 0.7, 1.0. 1.5 uL,) and values obtained were compared to YSI values. Results support the claimed sample volume of 0.7 µL.

6. EMC and electrical safety: As established previously in k153286 (BG1) and k153278 (BG5).

7. The device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the studies were conducted prior to the finalization of the guidance documents.

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.