

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

A. 510(k) Number:

k132086

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose from the finger, palm and forearm

D. Type of Test:

Quantitative Amperometric assay (FAD-Glucose Oxidase)

E. Applicant:

ACON Laboratories, Inc.

F. Proprietary and Established Names:

On Call Express Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1345, Glucose test system

21 CFR 862.1660, Quality Control Material (assayed and unassayed)

2. Classification:

Class II,

Class I (reserved)

3. Product code:

NBW, System, Test, Blood Glucose, Over The Counter

CGA, Glucose Oxidase, Glucose

JJX, Quality Control Material (Assayed and Unassayed)

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indication(s) for use below.

2. Indication(s) for use:

The On Call® Express Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips, forearm and palm by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. Alternative site testing should be done only during steady-state times (when blood glucose level is not changing rapidly).

The On Call® Express Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. It is for in vitro diagnostic use only.

The On Call® Express Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes, nor intended for use on neonates.

The On Call® Express Blood Glucose Test Strips are used with the On Call Express Blood Glucose Meter in the quantitative measurement of glucose in capillary blood from the fingertips, forearm and palm.

The On Call® Express Blood Glucose Control Solution is for use with the On Call® Express Blood Glucose Meter and Strips as a quality control check to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):

- For over-the-counter use
- Not for screening or diagnosis of diabetes mellitus
- Not for use on critically ill patients, patients in shock, patient severely dehydrated, or hyper-osmolar patients (with or without ketosis)
- 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
- Not for neonatal use
- For single-patient use only

4. Special instrument requirements:

On Call® Express glucose meter

I. Device Description:

The On Call® Express Blood Glucose Monitoring System contains a blood glucose meter and On Call Express blood glucose test strips. This is a no code meter. The 3-Level

control solution material (Level 0, Level 1 and Level 2), Owner’s booklet and carrying case are provided in the kit. Lancing device, and sterile lancets are optional/sold separately.

Control solution(s) is/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 On Call Express Blood Glucose Monitoring System.

J. Substantial Equivalence Information:

1. Predicate device name(s):
On Call ® Vivid Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
k112653
3. Comparison with predicate:

Example:

Similarities and Differences		
Item	Predicate Device On Call ® Vivid Blood Glucose Monitoring System (k112653)	Candidate Device On Call Express Blood Glucose Monitoring System
Intended Use/Indications for Use	It 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
Setting	Single patient use	Same
Detection method	Amperometry	Same
Enzyme	FAD-Glucose Oxidase	Same
Calibration Coding	Non-Coding	Same
Memory	500 records with time and date	300 records with time and date
Test range	20 - 600 mg/dL	Same

Sample type	Capillary whole blood	Same
Sample sites	Fingertip, forearm, palm	Same
Sample volume	0.8 µL	0.4
Sample test time	5 seconds	4 seconds
Hematocrit range	25 - 70%	30-55%
Altitude Study	Up to 8,516 feet	Same

Similarities and Differences for Control Solutions		
Item	Predicate Device On Call ® Vivid Blood Glucose Control Solution (k112653)	Candidate Device On Call Express Control Solutions
Intended use/Indications for Use	To check that the glucose meter and test strips are working together properly	Same
Matrix	Viscosity-adjusted, aqueous liquid	Same
Number of levels	2 levels (Level 1, Level 2)	3 levels (Level 0, Level 1 and Level 2)

K. Standard/Guidance Document Referenced:

- EN ISO 15197: 2003 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
- EN ISO 15197: 2013 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, Second Edition 2013-05-15.
- EN 1113 7-1: 2006 Sterilization of health care products. Radiation. Requirements for development, validation and routine control of a sterilization process for medical devices
- EN 11137-2: 2007 Sterilization of health care products. Radiation. Part 2: Establishing the sterilization dose
- EN 11137-3: 2006 Sterilization of health care products. Radiation. Guidance on dosimetric aspects
- EN 556-1:2001/AC: 2006 Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices
- EN 1173 7-1: 2006 Sterilization of medical devices. Microbiological methods. Determination of a population of microorganisms on products

- EN 11737-2: 2000 Sterilization of medical devices. Microbiological methods. Tests of sterility performed in the validation of a sterilization process
- EN 11607-1: 2006 Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems
- EN 10993-5: 2009 Biological evaluation of medical devices. Tests for in vitro cytotoxicity
- EN 10993-10: 2009 Biological evaluation of medical devices. Tests for irritation and delayed-type hypersensitivity
- EN 61326-1: 2006 Class B Electrical Equipment for Measurement, Control and Laboratory Use- EMC Requirements
- EN 61326-2-6: 2006 Electrical Equipment for Measurement, Control and Laboratory Use. Particular requirements. In vitro diagnostic (IVD) medical equipment
- IEC/EN 61010-1: 2001 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use. Part 1: General Requirements
- IEC/EN 61010-2-10: 2002 Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment
- EN ISO 14971 :2009 Medical devices - Application of Risk management to medical devices
- ISO 13640: 2002 Stability testing of in vitro diagnostic reagents
- EN 62366: 2008 Medical devices. Application of usability engineering to medical devices
- EN 62304: 2006 Medical device software. Software life-cycle processes
- CLSI EP-6A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
- CLSI EP7-A2 Interference Testing in Clinical Chemistry; Approved Guideline Second Edition
- ISO GP14-A: 1996 Labeling of Home-Use In Vitro Testing Products; Approved Guideline
- FDA Guidance for Industry In Vitro Diagnostic Glucose Test System; Final
- Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology
- Draft Guidance for Industry and FDA Staff- Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff: January 2002
- Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87 -1 #8294) (blue book memo)(Text Only)

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 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:

a. Precision/Reproducibility

Within-run (Repeatability)

Venous blood was adjusted with glucose to five glucose levels (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL) across the claimed range and tested on three lots of test strips on 10 meters (10 strips per meter). Ten replicates were tested per meter, test strip lot and glucose concentration (300 measurements per glucose level). Results are summarized below:

Glucose Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
30-50	100	1	43.1	1.20	2.8
		2	44.3	1.57	3.5
		3	43.6	1.44	3.3
51-110	100	1	84.6	1.97	2.3
		2	86.1	2.48	2.9
		3	87.0	2.76	3.2
111-150	100	1	127.5	3.30	2.6
		2	132.6	3.25	2.5
		3	128.8	2.81	2.2
151-250	100	1	189.0	3.67	1.9
		2	187.9	4.38	2.3
		3	190.7	5.09	2.7
251-400	100	1	316.7	8.66	2.7
		2	312.5	10.46	3.3
		3	306.9	8.58	2.8

Intermediate Precision

Intermediate precision was evaluated using three lots of test strips and ten meters. Glucose control solutions in three concentration ranges were used (Level 1, Level 2 and Level 3 or 50, 120, and 350 mg/dL). For each test strip lot, each control solution was measured once per day on 10 meters in replicates of 10, with three test strip lots for 10 days, so that 100 individual measurements were generated (300 measurements per glucose level). Results are summarized below:

Control Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
Level 1 30 - 50	100	1	41.8	1.52	3.6
		2	41.0	1.31	3.2

		3	40.0	1.26	3.1
Level 2 96 - 144	100	1	122.4	3.26	2.7
		2	117.8	3.30	2.8
		3	116.3	2.74	2.4
Level 3 280 - 420	100	1	332.1	13.9	3.9
		2	332.4	7.18	2.2
		3	331.9	11.46	3.5

b. *Linearity/assay reportable range:*

Linearity was evaluated using 3 lots of test strips, 2 meters, and 11 venous whole blood samples with glucose levels ranging from 20-600 mg/dL (13.4, 22.0, 46.9, 83.0, 107.9, 179.0, 219.6, 328.6, 451.5, 575.5, 637.8 mg/dL), obtained by spiking pooled venous blood with a glucose solution. Each glucose level was tested with 4 test strips over 3 test strip lots. Linear regression analysis for each test strip lot compared to the YSI resulted in:

$$y = 0.9871x + 0.1910; R^2 = 0.9991 \text{ for Test Strip Lot 1}$$

$$y = 0.9755x - 0.5512; R^2 = 0.9993 \text{ for Test Strip Lot 2}$$

$$y = 0.9685x + 1.6098; R^2 = 0.9992 \text{ for Test Strip Lot 3}$$

The measuring range of the On Call Express Blood Glucose Monitoring System is 20 - 600 mg/dL.

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

The On Call Express Blood Glucose Monitoring System is traceable to the NIST SRM 917b reference material. The method comparison study was performed using the candidate device and YSI as the reference method.

Value assignment:

The value assignment of the On Call Express Blood Glucose control solutions were determined by an in-house procedure. The 3 levels of control solutions (Levels 0, 1 and 2) are prepared by gravimetric addition of glucose to achieve target glucose values and are confirmed by the YSI method. Verification of the control solutions are tested with 240 test strips and 2 On Call Express meters with each level and the values were within the target ranges.

Stability:

Accelerated stability studies were conducted to assess the shelf-life and open vial stability of the control solutions and test strips with on-going real-time stability studies. Unopened control solutions have a 24 month shelf life and are stable for 4 months after first opening when stored at 41-86°F (5-30°C) and 10 – 90% relative humidity. The sponsor claims that the test strips be stored at 41-86 °F (5-30 °C) and

10-90% relative humidity and are stable for 5 months after first opening when stored at 41-86 °F (5-30 °C) and 10-90% relative humidity . The study protocols were reviewed and found to be adequate.

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on linearity studies above (section M.1.b.).

e. Analytical specificity:

To assess potential interference, the sponsor used venous whole blood samples adjusted to three glucose concentration intervals of 50-60 mg/dL, 100 - 120 mg/dL and 300-350 mg/dL. Each of these samples was divided into a test pool and a control pool and each of the potential endogenous and exogenous interfering substances was added to the test pool. Each substance was tested at a minimum of two concentrations, normal/therapeutic and high/toxic concentrations. The % difference between the test sample and the control sample was calculated. The sponsor defines no significant interference as $\leq \pm 10\%$ difference relative to the control sample. Results are presented in the table below:

Potential Interfering Substances	Concentration at which no significant interference is observed (mg/dL) (typical conc)
Acetaminophen	20
Ascorbic acid	3
Cholesterol	500
Conjugated-Bilirubin	50
Creatinine	5
Dopamine	0.9
Ethanol	400
Fructose	100
Galactose	100
Gentisic Acid	10
Glutathione	0.5
Hemoglobin	500
Ibuprofen	50
Lactose	25
L-Dopa	3
Maltose	100
Mannitol	600
Methyldopa	1.5
Salicylic Acid	60

Sorbitol	70
Tetracycline	1.5
Tolazamide	10
Tolbutamide	64
Triglycerides	3000
Unconjugated Bilirubin	40
Urea	600
Uric acid	23.5
Xylose	200

The labeling states the following: Interference might occur when the values of the limiting concentrations of these compounds are greater than those listed below:

Ascorbic acid > 3 mg/dL

Acetaminophen > 20 mg/dL

Bilirubin > 50 mg/dL

Uric Acid > 23.5 mg/dL

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device*

System accuracy was evaluated according to ISO 15197, 2003. Healthcare professionals tested 103 natural capillary blood samples collected from fingertips, forearms and palms and 8 altered samples (glycolyzed or spiked) ranging in glucose concentration from 40.9 to 574 mg/dL for fingertip and 50.4 to 498 mg/dL for palm and forearm, using 36 meters and 3 lots of test strips. Reference values were obtained on an YSI 2300 STAT PLUS analyzer. Results relative to YSI are summarized in the tables below:

Fingertip:

Linear Regression: On Call Express vs. YSI Reference			
Strip Lot	Linear regression equation	R ²	N
1	y = 0.9486x + 5.3824	0.9873	111
2	y = 0.9487x +	0.9862	111

	5.1409		
3	$y = 0.9441x + 5.7476$	0.9873	111

Forearm:

Linear Regression: On Call Express vs. YSI Reference			
Strip Lot	Linear regression equation	R ²	N
1	$y = 0.9918x + 5.433$	0.9766	103
2	$y = 0.9863x + 5.4172$	0.9802	103
3	$y = 0.9835x + 7.5921$	0.9822	103

Palm:

Linear Regression: On Call Express vs. YSI Reference			
Strip Lot	Linear regression equation	R ²	N
1	$y = 1.003x + 5.0984$	0.9761	103
2	$y = 1.0096x + 3.4377$	0.9828	103
3	$y = 1.0035x + 4.6809$	0.9793	103

Fingertip:

Glucose < 75 mg/dL

Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	11/15 (73.3%)	15/15 (100%)	15/15 (100%)
2	10/15 (66.7%)	15/15 (100%)	15/15 (100%)
3	11/15	15/15 (100%)	15/15 (100%)

	(73.3%)		
--	---------	--	--

Glucose \geq 75 mg/dL

Lot	Within \pm 5%	Within \pm 10 %	Within \pm 15 %	Within \pm 20 %
1	52/96 (54.2%)	85/96 (88.5%)	95/96 (99%)	96/96 (100%)
2	56/96 (58.3%)	86/96 (89.6%)	96/96 (100%)	96/96 (100%)
3	54/96 (56.3%)	86/96 (89.6%)	96/96 (100%)	96/96 (100%)

Forearm:

Glucose $<$ 75 mg/dL

Lot	Within \pm 5 mg/dL	Within \pm 10 mg/dL	Within \pm 15 mg/dL
1	5/10 (50%)	10/10 (100%)	10/10 (100%)
2	7/10 (70%)	10/10 (100%)	10/10 (100%)
3	7/10 (70%)	10/10 (100%)	10/10 (100%)

Palm:

Glucose $<$ 75 mg/dL

Lot	Within \pm 5 mg/dL	Within \pm 10 mg/dL	Within \pm 15 mg/dL
1	6/10 (60%)	10/10 (100%)	10/10 (100%)
2	8/10 (80%)	10/10 (100%)	10/10 (100%)
3	8/10 (80%)	10/10 (100%)	10/10 (100%)

Glucose $>$ 75 mg/dL

Lot	Within \pm 5%	Within \pm 10 %	Within \pm 15 %	Within \pm 20 %
-----	-----------------	-------------------	-------------------	-------------------

1	42/93 (45.2)	72/93 (77.4%)	91/93 (97.8%)	93/93 (100%)
2	39/93 (41.9%)	73/93 (78.5%)	90/93 (96.8%)	93/93 (100%)
3	36/93 (38.7%)	72/93 (77.4%)	93/93 (100%)	93/93 (100%)

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):

User performance study:

User performance study was performed to compare the lay user self-test results and the YSI method. Study was performed at one clinical site with 103 study subjects. The study participants were provided with the User's Manual in English, and performed fingerstick tests, forearm tests and palm tests on their own. A technician collected capillary blood from each participant for measurement on YSI. The range of glucose values was 50.4 to 498 mg/dL as measured by YSI. Three test strip lots were tested in the study. The results relative to YSI are summarized in the tables below:

Fingertip:

Linear Regression: On Call Express vs. YSI Reference			
Strip Lot	Linear regression equation	R ²	N

1	$y = 0.9762x + 1.8373$	0.9798	103
2	$y = 0.9599x + 4.1229$	0.9804	103
3	$Y = 0.9672x + 5.0504$	0.9835	103

Forearm:

Linear Regression: On Call Express vs. YSI Reference			
Strip Lot	Linear regression equation	R ²	N
1	$y = 0.9705x + 8.0497$	0.9788	103
2	$y = 0.9655x + 9.5634$	0.9763	103
3	$y = 0.9775x + 10.643$	0.9815	103

Palm:

Linear Regression: On Call Express vs. YSI Reference			
Strip Lot	Linear regression equation	R ²	N
1	$y = 1.008x + 4.413$	0.9837	103
2	$y = 1.0143x + 2.9536$	0.9825	103
3	$y = 0.9778x + 9.6711$	0.9801	103

Fingertip:

Glucose < 75 mg/dL

Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	7/10 (70.0%)	10/10 (100%)	10/10 (100%)
2	10/10 (100%)	10/10 (100%)	10/10 (100%)
3	9/10 (90%)	10/10 (100%)	10/10 (100%)

Glucose ≥ 75 mg/dL

Lot	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
1	56/93 (60.2%)	86/93 (92.5%)	93/93 (100%)	93/93 (100%)
2	43/93 (46.2%)	82/93 (88.2%)	93/93 (100%)	93/93 (100%)
3	52/93 (55.9%)	83/93 (89.2%)	93/93 (100%)	93/93 (100%)

Forearm:

Glucose < 75 mg/dL

Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	5/10 (50%)	10/10 (100%)	10/10 (100%)
2	5/10 (50%)	10/10 (100%)	10/10 (100%)
3	7/10 (70%)	10/10 (100%)	10/10 (100%)

Glucose ≥ 75 mg/dL

Lot	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
1	47/93 (50.5%)	74/93 (79.6%)	90/93 (96.8%)	93/93 (100%)
2	35/93 (37.6%)	68/93 (73.1%)	90/93 (96.8%)	93/93 (100%)

3	36/93 (38.7%)	67/93 (72%)	90/93 (96.8%)	93/93 (100%)
---	------------------	----------------	------------------	-----------------

Palm:

Glucose < 75 mg/dL

Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	5/10 (50%)	9/10 (90%)	10/10 (100%)
2	6/10 (60%)	9/10 (90%)	10/10 (100%)
3	5/10 (50%)	10/10 (100%)	10/10 (100%)

Glucose > 75 mg/dL

Lot	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
1	42/93 (45.2%)	72/93 (77.4%)	91/93 (97.8%)	93/93 (100%)
2	43/93 (46.2%)	74/93 (79.6%)	93/93 (100%)	93/93 (100%)
3	30/93 (32.3%)	71/93 (76.3%)	93/93 (100%)	93/93 (100%)

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

In the labeling the sponsor presents expected blood glucose levels for people without diabetes (referenced from the American Diabetes Association (2013), Diabetes Care, Vol. 36, Supplement 1.

N. Instrument Name:

On Call Express blood glucose meter

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and requires a sample volume of 0.4 uL.

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:

The glucose test is intended to be used with capillary whole blood from the finger, forearm and palm. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

There is no calibration required for the On Call Express blood glucose meter by the user. The meter is automatically coded.

6. Quality Control:

Glucose control solutions at 3 different concentrations are available to be run with this device and only one control level is provided with the kit. The meter automatically distinguishes control solution from blood and marks control solution tests with a check mark and excludes them from average calculations. Recommendations on when to test the control materials are provided in the labeling.

An acceptable range for each control level is printed on the test strip vial label and on the bottom of the test strip box. 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:

1. Sample volume study:

The sponsor performed a study to verify the test strip minimum sample volume requirement and the test strip fill error requirement established for the On Call Express blood glucose meter. Blood samples with 3 glucose concentrations were tested at five sample volumes (0.2, 0.3, 0.4, 0.5, and 0.6 μ L) and values obtained were compared to YSI values. Results support the claimed minimum sample volume of 0.4 μ L and the error code for insufficient sample volume of 0.3 μ L.

2. Altitude Study:

This study was conducted at a single site to evaluate the effect of altitude on the On Call Express Blood Glucose Monitoring System. The tested glucose range (obtained using YSI reference method) was from 45 to 480.5 mg/dL at sea level and 31.7 to 541.5 mg/dL at 8,516 ft above sea level. Fingerstick blood samples were collected and compared to the YSI analyzer reference value. These blood samples were evaluated using both the On Call Express BGMS and a YSI glucose analyzer. Each test strip glucose value was compared to the YSI method and then analyzed as a percent bias. The glucose values obtained using the On Call Express blood glucose meter had acceptable biases to support the altitude claim of 8,516 feet.

3. Hematocrit Study:

The sponsor performed hematocrit studies using 6 different hematocrit (30, 35, 40, 45, 50, and 55%) levels across the glucose measuring range (target glucose concentrations 40 – 50, 100 - 120, 280 - 300, and 500 – 550 mg/dL). 3 test strip lots were evaluated and compared to the YSI method. The results support the sponsor’s claimed hematocrit range of 30 –55%.

4. Test System operating conditions:

The effect of different temperature and humidity combinations on the performance of the system was assessed using three test strip lots tested at 7 combined temperature and relative humidity conditions 41 F(5°C)/10% RH, 69.8 F (21 °C)/ 10% RH, 113 F (45 °C)/10%, 41 F (5 °C)/90% RH, 69.8 F (21 °C)/ 90% RH, 113 F (45 °C)/ 90% RH, and 69.8 F (21 °C)/ 45% RH). Three blood samples were adjusted to the following glucose concentration levels: (40-60 mg/dL, 100-120 mg/dL, 500-550 mg/dL). Each sample was also compared to the YSI reference method. The results support the claims in the labeling that the system can be used

in temperatures ranging from 5 - 45°C and relative humidity conditions ranging from 10 – 90%.

5. Readability Assessment:

The readability of the labeling (user guides, test strip package insert and control solution package insert) using a Flesch-Kincaid analysis and were found to be written at the 8th grade level.

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

7. Software documentation:

The software documentation was reviewed and found to be acceptable. The firm provided documentation to support the device was designed, developed and is under good software lifecycle processes.

9. Infection Control Studies:

The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, (DisCide Ultra Wipes) Quaternary Ammonium/Isopropyl Alcohol disinfectant wipe (EPA Reg. No. 10492-4). This study was originally cleared in k112653. Robustness studies were also performed by the sponsor using the On Call Express BGMS and demonstrating that there was no change in performance or external materials of the meter after 260 times of cleaning and disinfection cycles, using (DisCide Ultra Wipes) Quaternary Ammonium/Isopropyl Alcohol disinfectant wipes, to simulate 5 years of use by layusers. 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.