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

A. 510(k) Number:

k123010

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative amperometric assay, glucose oxidase

E. Applicant:

ACON Laboratories, Inc.

F. Proprietary and Established Names:

On Call® Vivid Pro Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
NBW-system, test, blood glucose, prescription	Class II	21 CFR § 862.1345	75-Chemistry
CGA-glucose oxidase, glucose	Class II	21 CFR § 862.1345	75-Chemistry
JJX-single analyte control	Class I	21 CFR § 862.1660	75-Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

The On Call® Vivid Pro Blood Glucose Monitoring System is an electrochemical enzymatic assay. It is used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. The On Call® Vivid Pro Blood Glucose Monitoring System is intended for multiple patient use by health care professionals in health care facilities as an aid to monitoring the effectiveness of diabetes control programs. The system should only be used with single-use, auto-disabling lancing devices.

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

The On Call® Vivid Pro Blood Glucose Test Strips are used with the On Call Vivid Pro Blood Glucose Meter in the quantitative measurement of glucose in capillary blood from the finger.

The On Call® Vivid Pro Blood Glucose Control Solutions are for use with the On Call® Vivid Pro 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 in vitro diagnostic use only
- For Professional Use
- Not intended for use on neonates
- Not for diagnosis of or screening for diabetes mellitus
- Not to be used for patients who are dehydrated, hypotensive, in shock, critically ill or in a hyperosmolar state
- Meter should be cleaned and disinfected after use on each patient
- System should only be used with single-use, auto-disabling lancing devices.

4. Special instrument requirements:

The On Call® Vivid Pro Blood Glucose Meter

Only single-use auto-disabling lancing devices should be used with the On Call® Vivid Pro Blood Glucose Monitoring System.

I. Device Description:

The On Call® Vivid Pro Blood Glucose Monitoring System is a quantitative assay for the detection of glucose in capillary whole blood sampled from the fingertip. The glucose measurement is achieved by using the amperometric detection method.

The test strip has a reagent system including glucose oxidase and a mediator that reacts with glucose in the whole blood sample to produce an electrical current. This current is measured by the meter, and after calculation by the meter, the blood glucose concentration is shown on the meter display.

The On Call® Vivid Pro Blood Glucose Monitoring System consists of the On Call Vivid Pro Blood Glucose Meter, Carrying Case, User's Manual, Warranty Card and Logbook. Materials needed but not provided are the On Call Vivid Pro Blood Glucose Test strips, The On Call Vivid Pro Blood Glucose control solutions (Level I and Level II) and disposable, single use lancing devices.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   One Touch Ultra Blood Glucose Monitoring System

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

   k002134

3. Comparison with predicate:

Similarities		
Item	Device **On Call® Vivid Pro Blood Glucose Monitoring System**	Predicate **One Touch Ultra Blood Glucose Monitoring System (k002134)**
Intended Use/Indications for Use	Intended to be used for quantitative measurement of glucose in fresh capillary whole blood from the fingertip as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Methodology	Glucose oxidase biosensor	Same
Calibration	Plasma-equivalent	Same
Test time	5 seconds	Same
Sample Type	Fresh capillary whole blood from the fingertip	Same
Data Port	One serial data port-Data transmission was not evaluated in this submission.	Same
Measurement range	20 to 600 mg/dL	Same

Differences

Item	Device **On Call® Vivid Pro Blood Glucose Monitoring System**	Predicate **One Touch Ultra Blood Glucose Monitoring System (k002134)**
Minimum Sample size	0.8 µL	1.0 µL
Hematocrit Range	20-70%	30-55%
Operating Temperature	5-45˚C (41-113˚F)	6-44˚C (43-111˚F)
Coding	Auto Coding by meter. Automatic recognition of the intended coding after strip insertion	Manual Coding by manually selecting code by pressing button.
Meter memory	Up to 500 records with time and date	150 blood glucose and control solution tests
Power Source	Two (2) CR 2032 3.0V coin cell batteries	One (1) CR 2032 3.0V coin cell battery
Meter Size	Approximately 60g (with battery installed)	1.5 ounces with battery (Approximately 42g)

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

1. EN ISO 15197: 2003, In vitro diagnostic test systems - Requirements for In Vitro Whole Blood Glucose.
2. EN 11137 -1: 2006 Sterilization of healthcare products. Radiation. Requirements for development, validation and routine control of a sterilization process for medical devices.
3. EN 11137 – 2: 2007 Sterilization of healthcare products. Radiation. Part 2: Establishing the sterilization dose.
4. EN 11137 – 3: 2006 Sterilization of healthcare products. Radiation. Guidance on dosimetric aspects.
5. EN 61326 – 1: 2006 Class B Electrical Equipment for Measurement, Control and Laboratory Use. EMC Requirements. General Requirements.
6. EN 61326 – 2 – 6: 2006 Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements. Particular requirements. In vitro diagnostics (IVD) medical equipment.
7. EN 61010 – 1:2001 Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1. General requirements.
8. EN 556-1:2001 Sterilization of medical devices. Requirements for medical devoces to be designated “Sterile”. Requirements for terminally sterilized devices.
9. EN11607-1:2006 Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems.
10. EN 10993-5:2009 Biological evaluation of medical devices. Tests for in vitro cytotoxicity
11. EN 10993-10:2009 Biological evaluation of medical devices. Tests for irritation and delayed-type hypersensitivity.
12. IEC/EN 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment.
13. ISO 13640:2002 Stability testing of in vitro diagnostic reagents
14. EN 62366:2008 Medical Devices. Application of usability engineering to medical

devices.

15. EN 62304: 2006 Medical Device Software. Software life-cycle processes
16. ISO 14971: 2009 Medical devices – Application of Risk management to medical devices
17. CLSI EP-6 Evaluation of Linearity of Quantitative Measurement Procedures: A Statistical Approach

L. Test Principle:

The On Call® Vivid Pro Blood Glucose Monitoring System is a quantitative assay for the detection of glucose in fresh capillary whole blood from the fingertip. Amperometric technology is used for the detection of glucose from testing the strip (with whole blood sample) on the meter.

Reagent consisting of glucose oxidase and mediator is deposited onto the reaction cell section of the test strip with printed electrodes. When a drop of whole blood sample is applied to the reaction cell on the test strip, glucose in the blood sample reacts in the presence of glucose oxidase and mediator, and the reaction yields electrons. Thus, a current signal is produced from the reaction and detected by the meter. The detected current signal is then calculated by the meter, and glucose concentration reading is then displayed on the meter display.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:
   The sponsor performed within-run precision studies using heparinized venous blood samples at five different glucose concentrations. Each sample was tested on 3 lots of test strips on 10 meters. Ten replicates were tested per meter, test strip lot, and glucose concentration, (N=100 per test strip) for a total 300 measurements for each glucose level. Results are summarized below:

Glucose Level	30-50 (mg/dL)			50-110 (mg/dL)			110-150 (mg/dL)			150-250 (mg/dL)		
Test Strip Lot	1	2	3	1	2	3	1	2	3	1	2	3
Mean (mg/dL)	41.7	42.7	40.1	78.0	79.8	77.7	132.3	131.0	129.3	200.8	191.7	196.8
SD	1.6	1.6	1.3	3.1	2.5	2.7	4.0	4.0	3.7	4.4	4.4	5.8
CV%	3.9	3.7	3.2	3.9	3.1	3.5	3.0	3.1	2.8	2.2	2.3	3.0
n	100	100	100	100	100	100	100	100	100	100	100	100

Glucose Level	250-400 (mg/dL)		
Test Strip Lot	1	2	3
Mean (mg/dL)	278.0	272.7	273
SD	6.0	7.5	6.5
CV%	2.2	2.7	2.4
N	100	100	100

Intermediate precision was evaluated using three levels of glucose control solutions, Level 1, Level 2, and Level 3. Each control solution was tested using 10 test strips on 10 meters (1 test strip per meter). 3 test strip lots were tested for 10 days for a total 300 measurements for each glucose level. Results are summarized below:

Glucose Level	Level 1			Level 2			Level 3		
Test Strip Lot	1	2	3	1	2	3	1	2	3
Mean (mg/dL)	36.0	36.6	37.2	118.9	121.2	122.4	359.3	355.2	359.7
SD	1.6	1.5	1.6	3.4	3.4	4.2	8.5	11.6	11.0
CV%	4.4	4.1	4.2	2.8	2.8	3.5	2.4	3.3	3.0
n	100	100	100	100	100	100	100	100	100

b. Linearity/assay reportable range:

Linearity was evaluated using 11 venous blood samples ranging in glucose concentrations from 11.9 to 638.9 mg/dL (11.9, 28.0, 48.0, 78.7, 110.7, 168.5, 220.2, 326.4, 449.8, 549.4 and 638.9 mg/dL) as measured by the reference method. Each sample was tested in replicates of 4 on each of 3 test strip lots. The values obtained from the On Call® Vivid Pro Blood Glucose meter were compared to those obtained from the reference method. The results from regression analysis are summarized below:
Lot #1: $y=0.9998x+4.2445$; $R^2=0.999$
Lot#2: $y=1.0202x+2.8045$; $R^2=0.998$
Lot#3: $y=1.0318x+2.3263$; $R^2=0.999$

The results of the study support the claimed glucose measuring range of 20 to 600 mg/dL.

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

Traceability:

The On Call® Vivid Pro Blood Glucose Control solutions are traceable to the NIST SRM 917b reference material.

Control Value Assignment:

Value assignment is based on testing the control materials on multiple meters and test strip lots. Several replicates are performed on each level of control and a mean value is obtained. The mean value is then compared to a target value which has been established for each lot of control solution. Control solution ranges are provided on the test strip vial label. The protocols were reviewed and found to be adequate.

Stability:

Control Solutions: Accelerated stability studies were conducted to assess the shelf-life and open vial stability of the control solutions and test strips. Real-time stability studies are still on-going. Unopened control solutions have a 24 month shelf life and are stable for 6 months after first opening when stored at 2-30˚C (36-86˚F).

Test Strips: The sponsor claims that the unopened test strips have a 24 month shelf life and are stable for 6 months after opening when stored at 25-30˚C (77-86˚F).

This information is provided in the labeling of the test strips and control solution materials.

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on the linearity/reportable range studies above. The low and high detection limits for this device have been set at 20 and 600 mg/dL. Readings below 20 mg/dL and above 600 mg/dL will indicate a "Lo" and "Hi" on the meter display, respectively. See linearity study in Section M1b above.

e. Analytical specificity:

To assess potential interferences with the OnCall Vivid Pro system the sponsor used whole blood samples that were spiked to nominal glucose concentrations of 40-60 mg/dL, 80-120 mg/dL and 300-400 mg/dL. The interfering substances were prepared at 2 concentrations to include normal (therapeutic) and high (toxic). Each sample was analyzed in quadruplicate using three different lots of test strips. The sponsor defines no significant interference as ≤10% difference. Results are presented in the table below:

Potential Interfering Substance	Concentration at which no interference is observed		Potential Interfering Substance	Concentration at which no interference is observed
Acetaminophen	20 mg/dL		Maltose	100 mg/dL
Ascorbic Acid	3 mg/dL		Mannitol	600 mg/dL
Cholesterol	500 mg/dL		Methly Dopa	1.5 mg/dL
Conjugated Bilirubin	50 mg/dL		Salicylic Acid	60 mg/dL
Creatinine	5 mg/dL		Sorbitol	70 mg/dL
Dopamine	0.09 mg/dL		Tetracycline	1.5 mg/dL
Ethanol	400 mg/dL		Tolazamide	10 mg/dL
Fructose	100 mg/dL		Tolbutamide	64 mg/dL
Galactose	100 mg/dL		Triglycerides	3000 mg/dL
Hemoglobin	500 mg/dL		Unconjugated Bilirubin	40 mg/dL
Ibuprofen	50 mg/dL		Uric Acid	23.5 mg/dL
Lactose	25 mg/dL		Xylose	200 mg/dL
L-Dopa (Levo-Dopa)	3 mg/dL			

The sponsor has the following limitations in their labeling:

Acetaminophen, uric acid and ascorbic acid (vitamin C) (when occurring in blood at normal or at high therapeutic concentration) do not significantly affect results. However, abnormally high concentration in blood may cause inaccurately high results.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

To assess system accuracy, results from the On Call® Vivid Pro Blood Glucose Monitoring system were compared to results from YSI Model 2300 Stat Plus Glucose Analyzer (reference). Capillary samples from 105 participants with glucose concentrations ranging from 40.0- 562.5 mg/dL (capillary) by YSI method were analyzed. To obtain blood glucose concentrations <50mg/dL and > 400 mg/dL, 8 samples were allowed to glycolize or were spiked to achieve desired glucose concentrations. Three lots of test strips were used in the testing. The results relative to the reference method are summarized in the tables below:

Fingertip Sample Site On Call Vivid Result (vs. Plasma YSI with Fingertip sample):

System accuracy for glucose concentrations <75 mg/dL

Strip Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	13/17 (76.5%)	17/17 (100.0%)	17/17 (100.0%)
2	9/17 (52.9%)	17/17 (100.0%)	17/17 (100.0%)
3	12/17 (70.6%)	17/17 (100.0%)	17/17 (100.0%)
Combined	34/51 (66.66%)	51/51 (100.0%)	17/17 (100.0%)

System accuracy results for glucose concentrations ≥75 mg/dL

Strip Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
1	63/96 (65.6%)	88/96 (91.7%)	96/96 (100.0%)	96/96 (100.0%)
2	62/96 (64.6%)	85/96 (88.5%)	96/96 (100.0%)	96/96 (100.0%)
3	57/96 (59.4%)	86/96 (89.6%)	96/96 (100.0%)	96/96 (100.0%)
Combined	182/288 (63.2%)	259/288 (89.9%)	288/288 (100.0%)	288/288 (100.0%)

Linear Regression results On Call® Vivid Pro Blood Glucose **fingerstick** results vs. YSI Model 2300 Stat Plus Glucose Analyzer

Sample Site	Strip Lot	Slope	Intercept	R	R^2	N
Fingertip	1	1.0265	-1.8674	0.9947	0.9895	113
Fingertip	2	1.0018	1.2672	0.9942	0.9885	113
Fingertip	3	1.0083	-1.9030	0.9948	0.9895	113

b. Matrix comparison:

Not applicable. Only capillary whole blood samples are used.

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:

A user performance evaluation was performed to compare the lay user self-test results from capillary fingertip samples and the health technician results (fingertip samples from professional user) with the reference method (YSI). Studies were performed

with 105 lay user participants and 3 lots of test strips. The samples ranged from 48.0 to 444.0 mg/dL glucose as measured by the YSI (reference) method. A summary of the results received from one lot are summarized in the tables below:

Lay user vs. YSI:

Results for glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
7/12 (58.3%)	12/12 (100.0%)	12/12 (100.0%)

Results for glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
51/93 (58.3%)	83/93 (89.2%)	91/93 (97.8%)	93/93 (100.0%)

Health Technician vs. YSI

Results for glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
9/12 (75.0%)	12/12 (100.0%)	12/12 (100%)

Results for glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
62/93 (75.0%)	85/93 (91.3%)	93/93 (100.0%)	93/93 (100%)

Strip Lot	Tester	Linear Regression	R^2	N
MI1110428A	Layperson	y=1.0279x -5.7082	0.9957	105
MI1110428A	Technician	y=1.0421x -6.5499	0.9949	105

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   For people without diabetes[1]:

   Fasting and before meals: 70-100 mg/dL

   2 hours after meal: <140 mg/dL

   [1]ADA Clinical Practice Recommendations, 2011 Diabetes Care, 2011, Vol.34, supplement 1, S62-S69

N. Instrument Name:

On Call® Vivid Pro Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use only and requires a sample volume of 0.8µL.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:

   Yes _____ or No ___X_____

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

   Yes _____ or No _____X__

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 device is intended to be used with capillary whole blood from the fingertip. 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® Vivid Pro Blood Glucose meter. The meter is plasma-calibrated and is an auto coding meter. The coding information is on each test strip so the meter can recognize the coding information when each strip is inserted into the meter.

6. Quality Control:

Glucose control solutions (On Call® Vivid Pro Blood Glucose Control Solutions) at two different concentrations (control solution 1 and control solution 2)can be run with this device. The control solution 1 and control solution 2 are not provided with the meter. The ranges for the control solution are test strip dependant. An example of a lot specific range would be: control solution 1 (93-139mg/dL) control solution 2 (285-427 mg/dL). The meter has an algorithm to automatically recognize the control solutions to prevent control results from being stored in the internal memory as a patient result. 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:

1. Altitude Study:

   This study was conducted at a single site to evaluate the effect of altitude on the On Call Vivid Pro BGMS. The tested glucose range (obtained using YSI reference method) was tested at 8 different glucose concentrations from 41.7 to 567 mg/dL at sea level and 35.7 to 525 mg/dL at 8,516 ft above sea level. The glucose results obtained obtained using the On Call Vivid Pro blood glucose meter had acceptable biases to the reference to support the claim in the labeling that altitudes up to 8,516 feet have not significant affect on blood glucose measurements from the On Call Vivid Pro System.

2. Hematocrit Study:

   The effect of different hematocrit levels on the performance of the On Call Vivid Pro BGMS was evaluated using venous whole blood samples with 8 different hematocrit levels (20, 25, 30, 40, 50, 60, 65, and 70%) across the glucose measuring range (target glucose concentrations 50, 100, 275, and 500 mg/dL). Three test strip lots were evaluated and results from the On Call Vivid Pro BGMS compared to the YSI method. The results support the sponsor's claimed hematocrit range of 20 – 70%.

3. Temperature and Relative Humidity Study:

   Operating Conditions Study:
   The sponsor performed temperature and humidity studies using venous whole blood samples to evaluate temperatures ranging from 5˚C to 45˚C and relative humidity from 10% to 45%. In this study, three test strip lots were tested at 7 combined temperature and relative humidity conditions (5ºC/10% RH, 21 ºC/ 10% RH, 45 ºC/10%, 5 ºC/90% RH, 21 ºC/ 90% RH, 45 ºC/ 90% RH, and 21 ºC/ 45% RH). Three blood samples were adjusted to the following glucose concentration ranges: (40-60 mg/dL, 80-120 mg/dL, 500-550 mg/dL). Each sample was also compared to the YSI reference method. The results demonstrate that accurate readings can be obtained at temperatures ranging from 5 - 45ºC and relative humidity conditions ranging from 10 – 90%.

4. EMC Electromagnetic Compatibility and Electrical Safety verification testing of the On Call Vivid Pro Blood Glucose Monitoring System was performed and found to be adequate.

5. Sample volume study:
   The sponsor performed a sample volume study to demonstrate that 0.8µL of whole blood is sufficient volume for the On Call Vivid Pro blood glucose meter system. For this study, sample volumes ranging from 0.4µL – 1.0 µL were evaluated using three different lots of test strips. The blood glucose sample results collected using the On Call Vivid Pro blood glucose meter were compared with glucose values obtained with the YSI reference method and supported the minimum sample volume claim of 0.8 µL.

6. Infection control:

The device system is intended for multiple–patient use. 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 Wipes) disinfectant wipe (EPA Reg. No. 10492-4). Robustness studies were also performed by the sponsor demonstrating that there was not change in performance or external materials of the meter after 10,950 times of cleaning and disinfection cycles, using DisCide disinfectant wipes, to simulate 3 years of use by professional users. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. Readability Assessment:

A readability assessment was conducted on the user guides, test strip package insert and control solution package insert. It was determined that the readability of the labeling, using a Flesch-Kincaid analysis, were found to be written at the 7th grade level.

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.