DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ACON LABORATORIES, INC.
QIYI XIE
SR. STAFF REGULATORY AFFAIRS/CLINICAL AFFAIRS
10125 MESA RIM ROAD
SAN DIEGO CA 92121

September 5, 2015

Re: K151595
Trade/Device Name: On Call® Express Pro Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: June 12, 2015
Received: June 15, 2015

Dear Qiyi Xie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151595

Device Name
On Call® Express Pro Blood Glucose Monitoring System

Indications for Use *(Describe)*
The On Call Express Pro 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. The On Call Express 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 Express Pro Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, nor intended for use on neonates. Alternative site testing (AST) testing should only be done during steady-state times (when glucose is not changing rapidly).

The On Call Express Pro Blood Glucose Test Strips are used with the On Call Express Pro Blood Glucose Meter in the quantitative measurement of glucose in capillary blood from the fingertips, forearm and palm.
The On Call Express Pro Blood Glucose Control Solution is for use with the On Call® Express Pro Blood Glucose Meter and Strips as a quality control check to verify the accuracy of blood glucose test results.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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7. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is K151595

Submitter's Identification:

ACON Laboratories, Inc.

10125 Mesa Rim Road

San Diego, California 92121

Tel.: 858-875-8019
Fax: 858-875-8011

Date Prepared: August 18, 2015

Contact Person:

Qiyi Xie
Senior Staff, Clinical & Regulatory Affairs
Email: qxie@aconlabs.com

Proprietary Name of the Device:

On Call Express Pro Blood Glucose Monitoring System

Common Name:

Glucose Test System

Classification Name:

Class II §862.1345 Glucose Test System

Predicate Device:

On Call Express Blood Glucose Monitoring System
ACON Laboratories Inc
10125 Mesa Rim Rd,
San Diego, CA 92121

510(k) Number: K132086

Device Name: On Call Express Pro Blood Glucose Monitoring System

Proprietary Name	Classification	Product Code	Description	Common Name
On Call Express Pro Blood Glucose Monitoring System	862.1345 Class II	NBW	System, Test, Blood Glucose, Over The Counter	Glucose Test System
On Call Express Pro Blood Glucose Meter and On Call Express Pro Blood Glucose Test Strips	862.1345 Class II	CGA	Glucose Monitor	Glucose Meter & Test Strips
On Call Express Pro Glucose Control Solution	862.1660 Class I	JJX	Single Analyte Control	Control Solution

Device Description:

The On Call Express Pro Blood Glucose Monitoring System is a quantitative assay for the detection of glucose in capillary whole blood sampled from the fingertip, palm and forearm. 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 reading is displayed on the meter display, calibrated to a plasma reference.

The On Call Express Pro Blood Glucose Monitoring System contains a blood glucose meter and On Call Express Pro blood glucose test strips. This is a no code meter. The On Call Express Pro Blood Glucose Monitoring System consists of the On Call Express Pro Blood Glucose Meter, On Call Express Pro Blood Glucose control solutions (Level 0, Level 1 and Level 2), Carrying Case, User's Manual, Warranty Card and Logbook. Materials needed but not provided are the On Call Express Pro Blood Glucose Test strips and disposable, single use lancing devices.

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 Pro Blood Glucose Monitoring System

On Call Express Pro Blood Glucose Monitoring System has a data transfer function.

Data Port sends information to a computer via an optional data transfer cable. It allows users to view, analyze and print stored data in the meter. The data transfer cable is available for order as an optional add-on. The meter can transfer stored test results to a Windows-based personal

computer (PC) using an optional data transfer cable and the On Call® Diabetes Management Software (K131469). The software has been validated for use with On Call Express meter (K132086) which is the exact same device as On Call Express Pro meter.

Intended Use:

The On Call Express Pro 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. The On Call Express 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 Express Pro Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, nor intended for use on neonates. Alternative site testing (AST) testing should only be done during steady-state times (when glucose is not changing rapidly).

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

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

Technological Characteristics:

Specification of On Call Express Pro Blood Glucose Meter:

Feature	**Specification**
Measurement Range	20 to 600 mg/dL (1.1-33.3 mmol/L)
Result Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Minimum Sample Size	0.4 µL
Test Time	4 seconds
Power Source	One (1) CR 2032 3.0V coin cell battery
Battery Life	1,000 tests for glucose testing (not considering data transfer)
Glucose Units of Measure	The meter is preset to mg/dL when sold in the United States.
Memory	Up to 300 records with time and date
Automatic Shutoff	2 minutes after last action
Meter Size	3.46" x 1.93" x 0.65"
Display Size	1.38" x 1.26"
Weight	Approximately 50 g (with battery installed)
Operating Temperature	41-113°F (5-45°C)
Operating Relative Humidity	10-90% (non-condensing)
Hematocrit Range	30-55%
Data Port	9600 baud, 8 data bits, 1 stop bit, no parity

Special conditions for use statement(s):

- For in vitro diagnostic use only
- For Multiple Patient 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.

Special instrument requirements:

The On Call Express Pro Blood Glucose Meter

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

Substantial Equivalence:

Predicate device name:

On Call® Express Blood Glucose Monitoring System

Predicate 510(k) numbers:

K132086

Comparison with predicate:

Features	**On Call® Express Pro Blood Glucose Monitoring System**	**On Call® Express Blood Glucose Monitoring System (K132086)**
Similarities		
Indications for Use	The On Call® Express Pro 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 as an aid to monitoring the effectiveness of diabetes control programs.	Same
Detection Method	Amperometry	Same
Enzyme	FAD-Glucose Oxidase	Same
Calibration Coding	Non-coding	Same
Test Range	20 – 600 mg/dL	Same
Memory	300 records with time and date	Same

Sample Type	Capillary whole blood	Same
Sample sites	Fingertip, forearm, palm	Same
Sample Volume	0.4 µL	Same
Sample test time	4 seconds	Same
Hematocrit Range	30 – 55%	Same
Altitude Study	Up to 8516 feet	Same
Glucose Units of Measure	mg/dL	Same
Operating Temperature	41-113°F (5-45°C)	Same
Operating Relative Humidity	10–90%	Same
Data Port	One Serial data port	Same
Automatic Shutoff	Two minutes after last user action	Same
Power Source	One (1) CR 2032 3.0V coin cell battery	Same
Meter Size	3.46" x 1.93" x 0.65"	Same
Meter Weight	Approx. 50 g (with battery installed)	Same
Battery Life	Minimum of **1,000** measurements (without considering data transfer and test reminder alarms)	Same
Differences		
Intended Use/ Setting	Multiple patient use by health care professionals in health care facilities	Single Patient Use at home

Features	**On Call® Express Pro Blood Glucose Control Solution**	**On Call® Express Blood Glucose Control Solution (K132086)**
Indications for Use	To check that the glucose meter	Same

	and test strips are working together properly	
Matrix	Viscosity-adjusted, aqueous liquid	Same
Number of Levels	3 levels (Level 0, Level 1 and Level 2)	Same

Discussions of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Guidance documents included the "FDA Guidance for Industry In-Vitro Diagnostic Glucose Test System" and "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Laboratory Performance Testing:

The performance characteristics of the On Call Express Pro Blood Glucose Monitoring System were evaluated by performing the following studies: repeatability precision, intermediate precision, linearity, interfering agents, hematocrit effect, temperature effect evaluation – blood & control solution, low battery effect, altitude effect, sample volume, humidity effect, simulated shipping study – test strip & control solution, control value assignment, meter testing, software validation testing, electromagnetic compatibility and electrical safety testing as part of meter and strip validation testing.

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:

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

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

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

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

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

The On Call Express Pro 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 Pro 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 were

confirmed by the YSI method. Verification of the control solutions are tested with 240 test strips and 2 On Call Express Pro meters with each level and the values were within the target ranges.

Stability:
Accelerated and Real time 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 study. Unopened control solutions have a 24 month shelf life and are stable for 6 months after first opening when stored at 41-86ºF (5-30ºC) and 10 – 90% relative humidity. The test strips should be stored at 41-86 °F (5-30 °C) and 10-90% relative humidity and are stable for 6 months after first opening when stored at 41-86 °F (5-30 °C) and 10-90% relative humidity.

d. Detection limit:
The reportable range is 20 to 600 mg/dL based on linearity studies.

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 ≤ ±10 % difference relative to the control sample. Results are presented in the table below:

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

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

Discussion of Clinical Tests Performed:

Clinical studies were conducted with lay persons and trained laboratory technicians using the On Call Express Pro Blood Glucose Monitoring System. The study data were presented evaluating the system accuracy of the On Call Express Pro Blood Glucose Monitoring System compared to the YSI Model 2300 STAT PLUS (K913806) per the ACON Clinical Study Protocol for the Blood Glucose Monitoring System. In addition, the participating lay persons were questioned and responded as satisfied with the ease of operation by following the Instructions for Use in the User's Manual and the overall performance of the On Call Express Pro Blood Glucose Monitoring System.

Method comparison with predicate device:

The sponsor performed method comparison study to assess the performance of the On Call Express Pro Blood Glucose Monitoring System. 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 Pro vs. YSI Reference			
Strip Lot	Linear Regression equation	R^2	N
1	y = 0.9486x + 5.3824	0.9873	111
2	y = 0.9487x + 5.1409	0.9862	111
3	y = 0.9441x + 5.7476	0.9873	111

Forearm:

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

Palm:

Linear Regression: On Call Express Pro 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 (73.3%)	15/15 (100%)	15/15 (100%)

Glucose ≥ 75 mg/dL

Lot	Within ± 5%	Within ±10%	Within ± 15%	Within ± 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 ± 5 mg/dL	Within ±10 mg/dL	Within ± 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%)

Glucose ≥ 75 mg/dL

Lot	Within ± 5%	Within ±10%	Within ± 15%	Within ± 20%
1	45/93 (48.4%)	71/93 (76.3%)	91/93 (97.8%)	93/93 (100%)
2	40/93 (43.0%)	71/93 (76.3%)	90/93 (96.8%)	93/93 (100%)
3	41/93 (44.1%)	68/93 (73.1%)	93/93 (100%)	93/93 (100%)

Palm:

Glucose < 75 mg/dL

Lot	Within ± 5 mg/dL	Within ±10 mg/dL	Within ± 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 ± 5%	Within ±10%	Within ± 15%	Within ± 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%)	93/93 (100%)	93/93 (100%)
3	36/93 (38.7%)	72/93 (77.4%)	92/93 (98.9%)	93/93 (100%)

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 Pro 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 = 0.9627x + 5.0504	0.9835	103

Forearm:

Linear Regression: On Call Express Pro 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 Pro 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%)	9/10 (90%)	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	6/10 (60%)	10/10 (100%)	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)	66/93 (71.0%)	93/93 (100%)	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%)

Conclusion:

The laboratory testing and clinical study results demonstrate that the On Call Express Pro Blood Glucose Monitoring System is safe, effective and easy-to-use. It also demonstrates that the On Call Express Pro Blood Glucose Monitoring System meets the accuracy requirements and as such is substantially equivalent to the On Call Express Blood Glucose Monitoring System, currently sold on the U.S. market (K132086).