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

A. 510(k) Number:
k151595

B. Purpose for Submission:
Modified Device – modifications were made to the materials of the meter, the name of the test system and the intended use (for use on multiple patients).

C. Measurand:
Capillary whole blood glucose from the finger, palm and forearm

D. Type of Test:
Quantitative Amperometric assay (Glucose Oxidase)

E. Applicant:
ACON Laboratories, Inc.

F. Proprietary and Established Names:
On Call Express Pro Blood Glucose Monitoring System

G. Regulatory Information:

Regulation Section	Classification	Product Code	Panel
21 CFR 862.1345	Class II	CGA, Glucose Oxidase,	Clinical Chemistry (75)
21 CFR 862.1345	Class II	NBW, System, Test, Blood Glucose, Over the Counter	Clinical Chemistry (75)
21 CFR 862.1660	Class I (exempt)	JJX, Quality Control Material (assayed and unassayed)	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 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.

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.

3. Special conditions for use statement(s):
   - For in vitro diagnostic use
   - For multiple patient use
   - Not intended for use on neonates
   - Not for diagnosis of or screening of diabetes mellitus
   - Not to be used for patients who are dehydrated, hypotensive, in shock critically ill or in a hyper-osmolar state
   - Meter should be cleaned and disinfected after use on each patient
   - System should only be used with single-use, auto-disabling lancing devices
   - 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 persons undergoing Oxygen therapy
   - For fresh capillary whole blood, not for use with serum or plasma samples.

4. Special instrument requirements:
   On Call Express Pro glucose meter

I. Device Description:

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 Test Strips and 3 levels of On Call Express Pro Glucose Control Solutions (Control Solution 0, Control Solution 1 and Control Solution 2), Carrying Case and User's Manual and single-use, auto-disabling lancing devices (On Call Safety Lancets). Test Strips, Control Solutions and single-use, auto-disabling lancing devices are required but not provided with the Meter and must be purchased separately.

The On Call Express Pro Blood Glucose Monitoring System that is the subject of this submission uses identical technology, software, measurement algorithm, test strips, and quality control solutions as the predicate device, the On Call Express Blood Glucose Monitoring System, which was cleared in k132086. The only differences between this device and the predicate are the name, labeling (for multiple patient use by health care professionals) and the materials of the meter.

Test strips are packaged in vials of 50 and also available individually packaged. Each test strip contains the following reagent compositions: Glucose Oxidase (from *Aspergillus niger*).

Each box of control solutions (Control Solution 0, Control Solution1, Control Solution 2) contains one vial of each control solution level (2.0 mL per vial) of viscosity-adjusted, buffered aqueous control solutions that contain known concentrations of d-glucose. Control solutions were previously cleared under k132086 as the On Call Express Blood Glucose Control Solutions and are being renamed under this submission.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   On Call Express Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
   k132086

3. Comparison with predicate:

Similarities and Differences		
Item	**Predicate Device** On Call Express Glucose Monitoring System (k132086)	**Candidate Device** On Call Express Pro Blood Glucose Monitoring System (k151595)
Intended Use/Indications for Use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood from the fingertips, forearm and palm as an aid to monitor the effectiveness of diabetes control in people with diabetes.	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood from the fingertips, forearm and palm as an aid to monitor the effectiveness of diabetes control in people with diabetes.
Use Setting	At home for single patient use only	Multiple patient use in a clinical setting.

Detection method	Amperometry	Same
Enzyme	Glucose Oxidase	Same
Calibration Coding	Non-Coding	Same
Memory	300 records with time and date	Same
Test range	20 - 600 mg/dL	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 8,516 feet	Same
Glucose Units of Measurement	The meter is preset to mg/dL when sold in the United States.	Same
Operating Temperature	41-113°F (5-45°C)	Same
Operating Relative Humidity	10-90% (non-condensing)	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	Approximately 50 g (with battery installed)	Same

Similarities and Differences for Control Solutions

Item	**Predicate Device** On Call Express Glucose Control Solution (k132086)	**Candidate Device** On Call Express Pro Control Solutions (k151595)
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	3 levels (Control Solution 0, Control Solution 1 and Control Solution 2)	Same

K. Standard/Guidance Document Referenced:

- 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
- 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 IS0-10993, '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. A blood sample is drawn into the test strip by capillary action, and reacts with reagents on the test strip. This reaction produces an electrical current which is proportional to the concentration of glucose in the samples. The electrical current is measured by the meter and is displayed to the user as a corresponding blood glucose level.

M. Performance Characteristics:

Technological characteristics of this device are unchanged relative to the predicate device (k132086). Performance characteristics were established in k132086 and as described below.

a. Precision/Reproducibility

Within-run and intermediate precision were established in k132086.

b. Linearity/assay reportable range:

Linearity and reportable range were established in k132086.

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

Traceability

Traceability is as described in k132086.

Stability and Expected Values

Value assignment:
Value assignment for the On Call Express Blood Glucose Control Solutions is as described in k132086.

Test Strip Stability:
Accelerated and real time stability studies were conducted to assess test strip shelf-life and open vial stability. The study protocols and acceptance criteria were reviewed and found to be adequate to support claims that test strips in vials and individually wrapped in foil pouches can be stored at 41-86 °F (5-30 °C) and 10-90% relative humidity and that test strips in vials are stable for 6 months after first opening when stored at 41-86 °F (5-30 °C) and 10-90% relative humidity.

Control Solution Stability:
Accelerated and real time stability studies were conducted to assess control solution open and closed vial stability. The study protocols and acceptance criteria were reviewed and found to be adequate to support claims that 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).

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

e. Analytical specificity:

Analytical specificity was established in k132086. The labeling states:

> 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

Performance of the On Call Express Pro Blood Glucose Monitoring System for use by trained professionals testing capillary samples from the fingertip, forearm, and palm was established in k132086.

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:

Performance of the On Call Express Pro Blood Glucose Monitoring System for lay-users self-testing of capillary samples from the fingertip, forearm, and palm was established in k132086.

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 as:

Time	Range (mg/dL)	Range (mmol/L)
Fasting and Before Meals	70-100	3.9-5.6
2 Hours After Meal	Less than 140	Less than 7.8

These ranges were cited from the ADA Standards of Medical Care in Diabetes 2015.

N. Instrument Name:

On Call Express Pro Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

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

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

Yes ____X____ or No _____

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

Yes _____ 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 glucose test is intended to be used with capillary whole blood from the fingertip, forearm, or 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 by calibration information embedded in the test strip.

6. Quality Control:

   Glucose control solutions at 3 different concentrations are available to be run with this device. The user marks control solution tests by selecting an option from the menu on the meter. Control solution tests are indicated on the display with a pound (#) sign, this is described in the labeling, and these test results are excluded from calculated average results. 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:**
   A minimal sample volume of 0.4 µL for the On Call Express Pro Blood Glucose Monitoring System and validation of the error code for insufficient sample volume was established in k132086.

2. **Altitude Study:**
   Use of the On Call Express Pro Blood Glucose Monitoring System at up to 8,516 ft above sea level was established in k132086.

3. **Hematocrit Study:**
   Use of the On Call Express Pro Blood Glucose Monitoring System with samples with a hematocrit range of 30 –55% was established in k132086.

4. **Test System operating conditions:**
   Use of the On Call Express Pro Blood Glucose Monitoring System at temperatures from 5-45ºC and relative humidity conditions ranging from 10-- 90% was established in k132086.

5. **Readability Assessment:**
   The readability of the labeling (user guides, test strip package insert and control solution package insert) was evaluated using a Flesch-Kincaid analysis and was found to be at the 8th grade level.

6. **EMC Testing:** As established in k132086.

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.

8. **Infection Control Studies:**

The device system is intended for multiple-patient use. Disinfection efficacy studies were performed on the materials comprising the meter in two previous submissions (k122110 and k111371) by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, DisCide Ultra Disinfecting Towelettes (EPA Reg. No. 10492-4). Robustness studies were also performed by the sponsor using the On Call Express Pro Blood Glucose Monitoring System and demonstrating that there was no change in performance of the system or external materials of the meter after 10,950 cleaning and disinfection cycles, using DisCide Ultra Wipes Disinfecting Towelettes, to simulate 3 years of

multiple patient use. 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.