October 3, 2018

ACON Laboratories, Inc.
Qiyi Xie
Senior Staff, Regulatory/Clinical Affairs
10125 Mesa Rim Road
San Diego, CA 92121

Re: K181527
Trade/Device Name: On Call Sure Blood Glucose Monitoring System
On Call Sure Sync Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: August 30, 2018
Received: August 31, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181527

Device Name
On Call Sure Blood Glucose Monitoring System

Indications for Use *(Describe)*
The On Call Sure Blood Glucose Monitoring System is comprised of the On Call Sure Blood Glucose Meter and On Call Sure Blood Glucose Test Strips. The On Call Sure 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 Sure Blood Glucose Monitoring System is intended for self-testing by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control programs. The On Call Sure Blood Glucose Monitoring System is intended for single-patient use and should not be shared.

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181527

Device Name
On Call Sure Sync Blood Glucose Monitoring System

Indications for Use *(Describe)*
The On Call Sure Sync Blood Glucose Monitoring System is comprised of the On Call Sure Sync Blood Glucose Meter and On Call Sure Blood Glucose Test Strips. The On Call Sure Sync 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 Sure Sync Blood Glucose Monitoring System is intended for self-testing by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control programs. The On Call Sure Sync Blood Glucose Monitoring System is intended for single-patient use and should not be shared.

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

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)

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5. 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 K181527.

Submitter's Identification:

ACON Laboratories, Inc.
10125 Mesa Rim Road
San Diego, California 92121

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

Date Prepared: October 1, 2018

Contact Person:

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

Proprietary Name of the Device:

On Call Sure Blood Glucose Monitoring System
On Call Sure Sync Blood Glucose Monitoring System

Common Name:

Glucose Test System

Classification Name:

Class II §862.1345 Glucose Test System

Predicate Device:

On Call Sharp Blood Glucose Monitoring System

ACON Laboratories, Inc.
10125 Mesa Rim Rd,
San Diego, CA 92121

510(k) Number: K130284

Device Name: On Call Sure Blood Glucose Monitoring System
On Call Sure Sync Blood Glucose Monitoring System

Proprietary Name	Classification	Product Code	Description	Common Name
On Call Sure and *On Call Sure Sync* Blood Glucose Monitoring System	862.1345 Class II	NBW	System, Test, Blood Glucose, Over the Counter	Glucose Test System

Device Description:

The On Call Sure Blood Glucose Monitoring System and On Call Sure Sync Blood Glucose Monitoring System are designed for the quantitative measurement of glucose in fresh capillary whole blood samples obtained from the fingertip, forearm, and/or palm

Both systems have almost the same meter design and use the same strip and control solution. The only difference is that On Call Sure Sync Blood Glucose meter is embedded with a Bluetooth module which results in an additional Bluetooth data transfer feature for this meter. Thus, the On Call Sure Blood Glucose Monitoring System and On Call Sure Sync Blood Glucose Monitoring System can be considered equivalent for the performance of glucose testing.

Both systems share the same On Call Sure Blood Glucose test strip. It has a reagent system that includes glucose dehydrogenase (FAD-GDH) and a mediator that reacts with the glucose in the whole blood sample to produce an electrical current signal. This current is measured using an amperometric detection method. The meter then calculates and displays the blood glucose concentration reading, calibrated to plasma reference. The On Call Sure / On Call Sure Sync Blood Glucose Meters are auto-coding.

Both systems consist of the On Call Sure / On Call Sure Sync Blood Glucose Meter, On Call Sure Blood Glucose Test Strips, and On Call Sure Glucose Control Solutions. Kits may be marketed with various combinations and quantities of the system components, or each of the components may be sold separately. All meter kits include a Carrying Case, User's Manual, Quick Reference Guide, Warranty Card and Logbook. Materials needed but not provided include a single user lancing device and sterile lancets.

The On Call Sure Glucose Control Solutions are used to confirm that the meter and test strips are working properly. Glucose control solution(s) is/are viscosity-adjusted, buffered aqueous control solutions that contain known concentrations of d-glucose. Two control solution levels are available (Level 1 and Level 2). Level 1 is provided with the system. Level 2 is sold separately.

Both meters have a USB data transfer function that is inactive, pending validation with the On Call Diabetes Management Software (K131469). Only the On Call Sure Sync Blood Glucose Meter is equipped with Bluetooth.

The On Call Sure Sync Blood Glucose Meter is designed with a Bluetooth module which can send glucose test results to a mobile device if the glucose meter and the mobile device are paired and within range.

Intended Use:

On Call Sure Blood Glucose Monitoring System

The On Call Sure Blood Glucose Monitoring System is comprised of the On Call Sure Blood Glucose Meter and On Call Sure Blood Glucose Test Strips. The On Call Sure 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 Sure Blood Glucose Monitoring System is intended for self-testing by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control programs. The On Call Sure Blood Glucose Monitoring System is intended for single-patient use and should not be shared.

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

On Call Sure Sync Blood Glucose Monitoring System

The On Call Sure Sync Blood Glucose Monitoring System is comprised of the On Call Sure Sync Blood Glucose Meter and On Call Sure Blood Glucose Test Strips. The On Call Sure Sync 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 Sure Sync Blood Glucose Monitoring System is intended for self-testing by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control programs. The On Call Sure Sync Blood Glucose Monitoring System is intended for single-patient use and should not be shared.

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

On Call Sure Test Strips

On Call Sure Test Strips are used with the On Call Sure and On Call Sure Sync Blood Glucose Meters in the quantitative measurement of glucose in capillary blood from the fingertips, forearm and palm.

On Call Sure Sync Glucose Control Solutions

On Call Sure Glucose Control Solutions are for use with the On Call Sure and On Call Sure Sync Blood Glucose Meters and Strips as a quality control check to confirm that the test strip and meter are working together properly, and that the user can perform the test correctly.

Technological Characteristics:

Specifications of the On Call Sure and On Call Sure Sync Blood Glucose Meters:

System	On Call Sure Blood Glucose Meter	On Call Sure Sync Blood Glucose Meter
Measurement Range	40-600 mg/dL	Same
Test Time	5 second	Same
Minimum Sample Size	0.6 uL	Same
Coding	Auto Coding	Same
Hematocrit Range	10-70%	Same
Insufficient Sample	Error message	Same
Control Recognition	Yes	Same
Strip Open Vial Stability	6 months from first opening	Same
Strip Closed Vial Stability	24 months (from DOM)	Same
Strip Storage Temperature	2°C - 35°C (36° - 95 ºF)	Same
Strip Storage Relative Humidity	10-90% R.H.	Same
Operating Temperature	5°C - 45°C (41° - 113 ºF)	Same
Operating Relative Humidity	10-90% R.H.	Same
Precision	≤5% CV	Same
Accuracy	Within +/-15% (95% data pts)	Same
Sample - Fresh capillary whole blood	Yes	Same
AST - Palm	Yes	Same
AST - Forearm	Yes	Same
Meter Memory	Up to 1000 records with time and date	Same
Day Average	7, 14, 30, 60 and 90-day averages	Same
Hypo & Hyper Indicator	Yes	Same
Test Reminder	Yes	Same
Meal Marker	Yes	Same
Meter Auto Power Off	2 minutes after last action	Same
Meter Audio	Yes	Same
Battery Type	Two (2) CR 2032 3.0V coin cell batteries	Same
Battery Life	3,000 glucose tests	3,000 glucose tests (not considering Bluetooth data transfer)
Strip Ejector	Yes	Same
Wireless Frequency (On Call Sure Sync Meter)	Not applicable	2.4 GHz worldwide ISM band(Instrumentation, Scientific and Medical); Bluetooth 4.2 Low Energy

Special conditions for use statement(s):

- For *in vitro* diagnostic use only
- For single patient use only; should not be shared
- 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
- Alternate site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations
- AST should only be done during steady-state times (when glucose is not changing rapidly)
- System should only be used with single patient use lancing device with sterile lancets.

Special instrument requirements:

The On Call Sure and On Call Sure Sync Blood Glucose Meter

- Single patient use lancing device with sterile lancets should be used with the On Call Sure and On Call Sure Sync Blood Glucose Monitoring System.
- Proper cleaning of the meter with qualified cleaning wipes is required.

Substantial Equivalence:

Predicate Device:

On Call Sharp Blood Glucose Monitoring System

ACON Laboratories Inc
10125 Mesa Rim Rd,
San Diego, CA 92121

510(k) Number: K130284

Comparison with predicate:

Feature	On Call Sure / On Call Sure Sync Blood Glucose Monitoring System	On Call Sharp Blood Glucose Monitoring System (K132084)
Indications for Use	The On Call Sure and On Call Sure Sync Blood Glucose Monitoring Systems are comprised of the On Call Sure or On Call Sure Sync Blood Glucose Meter and On Call Sure Blood Glucose Test Strips. The On Call Sure and On Call Sure Sync Blood Glucose Monitoring Systems are intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips, forearm and palm. The On Call Sure and On Call Sure Sync Blood Glucose Monitoring Systems are intended for self-testing by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control programs. The On Call Sure and On Call Sure Sync Blood Glucose Monitoring Systems are intended for single-patient use and should not be shared. The On Call Sure and On Call Sure Sync Blood Glucose Monitoring Systems are for in vitro diagnostic use. The On Call Sure and On Call Sure Sync Blood Glucose Monitoring Systems are not intended for the diagnosis of or screening for diabetes, nor intended for use on neonates. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).	The On Call Sharp Blood Glucose Monitoring System is an electrochemical enzymatic assay for the quantitative detection of glucose in fresh capillary whole blood from the fingertip, forearm, and palm by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. Forearm and palm testing sites should be used alternately only when blood glucose level is not changing rapidly. The On Call Sharp 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.
Detection Method	Amperometric electrochemical	Same
Enzyme	Glucose Dehydrogenase (FAD-GDH)	same
Calibration Coding	Auto-coding	Non-coding
Test Range	40 – 600 mg/dL	20 – 600 mg/dL
Memory	1000 records with time and date	500 records with time and date
Sample Type	Capillary whole blood	Same
Sample Sites	Fingertip, forearm, palm	Same
Sample Volume	0.6 µL	0.8 µL
Sample Test Time	5 seconds	same
Hematocrit Range	10 – 70%	25 – 70%
Altitude Study	Up to 10000 feet	Up to 8516 feet
Glucose Units of Measure	mg/dL	Same

Feature	On Call Sure / On Call Sure Sync Blood Glucose Monitoring System	On Call Sharp Blood Glucose Monitoring System (K132084)
Operating Temperature	41-113°F (5-45°C)	50-113°F (10-45°C)
Operating Relative Humidity	10–90%	Same
Data Port	Serial data port	Same
Automatic Shutoff	Two minutes after last user action	Same
Power Source	Two CR 2032 3.0V coin cell batteries	same
Meter Size	90 x 60 x 16 mm	90 x 58 x 22 mm
Meter Weight	Approx. 72 g (with batteries installed)	Approx. 50 g (with battery installed)
Battery Life	Minimum of 3,000 measurements (without considering data transfer and test reminder alarms)	Minimum of 1,000 measurements (without considering data transfer and test reminder alarms)

Non-Clinical Tests Performed for Determination of Substantial Equivalence

Standard/Guidance Documents Referenced:

- FDA Guidance for Industry and Food and Drug Administration Staff - Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use
- Draft Guidance for Industry and FDA Staff - Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems
- Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology
- 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
- **CLSI/NCCLS EP06-A:** Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
- **CLSI/NCCLS EP07-A2:** Interference Testing in Clinical Chemistry; Approved Guideline Second Edition
- **EN ISO 13485:2012/AC:2012:** Medical devices - Quality management systems - Requirements for regulatory purposes
- **EN 13532:2002:** General requirements for in vitro diagnostic medical devices for self-testing
- **EN 13612:2002/AC:2002:** Performance evaluation of in vitro diagnostic medical devices
- **EN 13640:2002/EN 13640:2002:** Stability testing of in vitro diagnostic reagents
- **EN 13641:2002:** Elimination or reduction of risk of infection related to in vitro diagnostic reagents
- **EN ISO 14971:2012:** Medical devices - Application of Risk management to medical devices
- **EN ISO 15197:2015:** In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
- **EN ISO 15223-1:2016:** Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2016-12-15)
- **EN ISO 17511:2003:** In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials

- **EN ISO 18113-1:2011:** In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling). Part 1: Terms, definitions and general requirements
- **EN ISO 18113-2:2011:** In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling). Part 2: In vitro diagnostic reagents for professional use
- **EN ISO 18113-3:2011:** In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 3: In vitro diagnostic instruments for professional use
- **EN ISO 18113-4:2011:** In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling). Part 4: In vitro diagnostic reagents for self-testing
- **EN ISO 18113-5:2011:** In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 5: In vitro diagnostic instruments for self-testing
- **EN 13640:2002:** Stability testing of in vitro diagnostic reagents
- **IEC 60068-2-64:2008:** Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance
- **IEC/EN 61010-1:2010:** Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements
- **IEC 61010-2-101:2015:** Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- **IEC 60601-1-2:2014:** International Standard: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances - Requirements and tests
- **EN 62366:2008:** Medical devices. Application of usability engineering to medical devices
- **EN 62304:2006 / AC:2008:** Medical device software. Software life-cycle processes
- **ASTM D 4169-09A:** Standard Practice for Performance Testing of Shipping Containers and Systems
- **Council Directive 2002/95/EC:** on Waste Electrical and Electronic Equipment (WEEE Directive)
- **Council Directive 80/181/EEC of 20 December 1979:** EU Metric Directive
- **Council Directive 1999/103/EC:** amending council directive 80/181/ECC on the approximation of the laws of Member States relating to units of measurement
- **Directive 2011/65/EU:** on the restriction of the use of certain hazardous substances in electrical and electronic equipment
- **EN 50581:2012:** Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
- **IEC 62321:2008:** Electrotechnical products - Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers)

Laboratory Performance Testing:

The performance characteristics of the On Call Sure and On Call Sure Sync Blood Glucose Monitoring System were evaluated in 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

Repeatability Precision

Ten replicate assays were each run on ten On Call Sure Sync Blood Glucose Meters. Heparinized venous blood samples at six concentration levels were used in the testing. The results provided the following estimates for reproducibility, and precision.

MEAN	42.6 mg/dL	82.2 mg/dL	133.3mg/dL	205.1mg/dL	334.6 mg/dL	517.6 mg/dL
Standard Deviation mg/dL or Coefficient of Variation (CV)	1.24 mg/dL	2.28 mg/dL	2.5 %	2.5 %	2.6 %	2.2 %

Intermediate Precision

Ten replicate assays drawn from three strip lots were run on ten On Call Sure Sync Blood Glucose Meters. These tests were run each day for a total of ten days. Control solutions at six concentration levels were used in the testing. The results provided the following estimates.

#	MEAN	Standard Deviation (mg/dL) or Coefficient of Variation (CV)
Strip Lot 1	36.0 mg/dL	0.91 mg/dL
	67.7 mg/dL	1.50 mg/dL
	128.1 mg/dL	2.3 %
	167.5 mg/dL	1.9 %
	321.0 mg/dL	2.1 %
	432.2 mg/dL	2.3 %
Strip Lot 2	35.8 mg/dL	1.09 mg/dL
	67.6 mg/dL	1.77 mg/dL
	127.8 mg/dL	2.7 %
	167.8 mg/dL	2.5 %
	320.9 mg/dL	2.0 %
	426.5 mg/dL	1.9 %
Strip Lot 3	36.0 mg/dL	1.05 mg/dL
	67.6 mg/dL	1.57 mg/dL
	127.5 mg/dL	2.7 %
	168.4 mg/dL	2.2 %
	319.9 mg/dL	1.6 %
	420.7 mg/dL	1.8 %

b) Linearity/assay reportable range:

Linearity was evaluated using 3 lots of test strips, 10 meters, and prepare blood sample to 42%±2% hematocrit level checked by Hematocrit Reader. Prepare eleven blood glucose concentration levels as shown in Table 1. The glucose concentration in venous blood samples may be adjusted by supplementing the sample with an around 20% aqueous glucose solution. (The aqueous glucose solution for blood sample glucose spiking shall be allowed to stand for at least 2 hours before use to allow for complete mutarotation and equilibration of the D and L enantiomers.) Each blood glucose concentration is tested by YSI Glucose Analyzer as shown in the following table:

Level	Glucose Concentration Level (mg/dL) Plasma YSI Value
10	5-20 mg/dL
25	20 -30 mg/dL
50	40 - 60 mg/dL
80	70 - 90 mg/dL
110	100 -120 mg/dL
170	160 -180 mg/dL
220	210 - 230 mg/dL
330	310 - 350 mg/dL
450	430 - 470 mg/dL
550	520 - 580 mg/dL
650	600 - 700 mg/dL

Linear regression analysis for each test strip lot compared to the YSI:

$y = 1.0055x + 0.3755$; $R^2 = 0.9976$ for Test Strip Lot 1

$y = 1.0023x - 0.3007$; $R^2 = 0.9976$ for Test Strip Lot 2

$y = 0.9948x + 0.4345$; $R^2 = 0.9991$ for Test Strip Lot 3

The linear range of the On Call Sure and On Call Sure Sync Blood Glucose Monitoring System is 10-600 mg/dL.

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

The On Call Sure and On Call Sure Sync 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 Sure and On Call Sure Sync Blood Glucose control solutions were determined by an in-house procedure. 2 levels of control solutions (Levels 1 and 2) were prepared by gravimetric addition of glucose to achieve target glucose values and were confirmed by the YSI reference method. Verification of the control solutions was done by testing with 80 test strips and at least 2 meters with each level, and the values were within the target ranges.

d) 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 study. Unopened control solutions have a 24 month shelf life and are stable for 6 months after first opening when stored at 36-95ºF (2-35ºC) and 10 – 90% relative humidity. The unopened test strips have a 24 month shelf life and are stable for 6 months after first opening when stored in a cool, dry place between 36-95°F (2-35°C) and 10-90% relative humidity and kept out of direct sunlight.

e) Detection limit:

The reportable range is 40-600 mg/dL based on clinical study lab testing results.

f) Analytical specificity:

To assess potential interference, the sponsor used venous whole blood samples adjusted to three glucose concentration intervals of 50-70 mg/dL, 110 - 130 mg/dL and 250-270 mg/dL. Blood samples were adjusted to a hematocrit level of 42%±2% and checked by a hematocrit reader. The interfering substance samples of both the Test Pool and Control Pool were prepared with the respective substance concentrations in the following table. Test Pool samples were prepared to the specified concentrations. Control Pool samples were prepared with the same solvent without the substance. Results are shown below:

Interfering Substance	**Therapeutic / Physiological Level**	**Test Concentration**		**On Call Sure and On Call Sure Sync Systems**
		Low	**High**	
Acetaminophen	1.0-3.0 mg/dL	4 mg/dL	20 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Ascorbic Acid	0.4-2.0 mg/dL	3 mg/dL	6 mg/dL	NO INTERFERENCE at therapeutic levels and levels ≤ 3.0 mg/dL*
Cholesterol	114-300 mg/dL	250 mg/dL	500 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Conjugated-Bilirubin	<0.4 mg/dL	34 mg/dL	50 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Creatinine	0.6-1.3 mg/dL	1.5 mg/dL	10 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration

Interfering Substance	Therapeutic / Physiological Level	Test Concentration		On Call Sure and On Call Sure Sync Systems
		Low	High	
Dopamine	0.03 mg/dL	0.03 mg/dL	20 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
EDTA	180 mg/dL	100 mg/dL	200 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Ephedrine	0.001 mg/dL	0.1 mg/dL	0.5 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Ethanol	100-200 mg/dL	200 mg/dL	400 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Fructose	1-6 mg/dL	30 mg/dL	100 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Galatitol		0.03 mg/dL	0.09 mg/dL	NO INTERFERENCE at levels up to high test concentration
Galactose	4-80 mg/dL	78 mg/dL	100 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Gentisic acid	0.2-0.6 mg/dL	10 mg/dL	100 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Glutathione (Reduced)	47-100 mg/dL (Intracellular)	0.1 mg/dL	92 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Hemoglobin	100-200 mg/dL	200 mg/dL	2000 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Heparin Sodium	350-1000 u/L	3000 u/L	80000 u/L	NO INTERFERENCE at therapeutic levels up to high test concentration
Ibuprofen	1.0-7.0 mg/dL	7 mg/dL	50 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Isomalt		0.03 mg/dL	0.09 mg/dL	NO INTERFERENCE at levels up to high test concentration
Lactitol		0.03 mg/dL	0.09 mg/dL	NO INTERFERENCE at levels up to high test concentration

Interfering Substance	Therapeutic / Physiological Level	Test Concentration		On Call Sure and On Call Sure Sync Systems
		Low	High	
Lactose	0.5 mg/dL	5 mg/dL	25 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
L-Dopa (Levo-Dopa)	0.02-0.3 mg/dL	0.3 mg/dL	3 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Maltitol		0.03 mg/dL	0.09 mg/dL	NO INTERFERENCE at levels up to high test concentration
Maltose	100 mg/dL	40 mg/dL	10000 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Mannitol	0.0128 mg/dL	300 mg/dL	600 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Methyl Dopa	0.1-0.75 mg/dL	0.75 mg/dL	1000 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Paralidoxime Idodine (PAM)		25 mg/dL	80 mg/dL	NO INTERFERENCE at levels up to high test concentration
Salicylic Acid	10-30 mg/dL	30 mg/dL	60 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Sodium			414 mg/dL	NO INTERFERENCE at levels up to high test concentration
Sorbitol	0.044mg/dL	30 mg/dL	70 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Tetracycline	0.2-0.5 mg/dL	0.5 mg/dL	1.5 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Tolazamide	2.0-2.5 mg/dL	5 mg/dL	40 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Tolbutamide	5.4-10.8 mg/dL	11 mg/dL	100 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Triglycerides	150-500 mg/dL	1500 mg/dL	3000 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration

Interfering Substance	Therapeutic / Physiological Level	Test Concentration		On Call Sure and On Call Sure Sync Systems
		Low	High	
Unconjugated-Bilirubin	0.3-1.3 mg/dL	20 mg/dL	40 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Urea	6.6-85.8 mg/dL	260 mg/dL	600 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Uric Acid	2.5-8.0 mg/dL	8 mg/dL	24 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Xylitol		0.03 mg/dL	0.09 mg/dL	NO INTERFERENCE at levels up to high test concentration
Xylose	20-40 mg/dL	1 mg/dL	200 mg/dL	INTERFERENCE at levels of 90 mg/dL and 200 mg/dL; NO INTERFERENCE at levels ≤ 6 mg/dL**

* Ascorbic Acid precaution (labeling) is needed based on FDA guidance and CLSI guidance differences.

**The results showed no significant interference on the OC Sure Sync Blood Glucose Monitoring System when Xylose was ≤6 mg/dL.

Discussion of Clinical Tests Performed:

The clinical study protocol followed "FDA Guidance for Industry and Food and Drug Administration Staff- Self--Monitoring Blood Glucose Test Systems for Over-the-Counter Use (2016)." The clinical studies were conducted with lay persons using the On Call Sure Sync Blood Glucose Monitoring System. The study data were presented evaluating the system accuracy of the On Call Sure Sync 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. Study results indicate that non-professional, inexperienced lay persons were able to obtain comparable blood glucose readings when using the On Call Sure Sync Blood Glucose Monitoring System as compared to the YSI 2300 glucose measurement results obtained by the trained technicians. 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 Sure Sync Blood Glucose Monitoring System.

Method comparison with device:

Part I: User Evaluation Study

Based on "FDA Guidance for Industry and Food and Drug Administration Staff-Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use (2016)," study participants were recruited to assess the system accuracy by measuring the blood glucose levels of finger, palm, and forearm capillary blood samples both on their own using the On Call Sure Sync Blood Glucose Monitoring System and 3 lots of test strips..

366 subjects participated in the study with 3 lots of strips (n=122/lot), including 38 subjects who indicated in the Case Report Form that they were naïve users of blood glucose monitoring systems.

Each study subject was sequestered in an air-conditioned room with a window, furnished with a table and chairs, to simulate an OTC intended use environment. Each subject was given 1 lot of test strips, obtained and tested his/her own capillary blood sample to perform the blood glucose measurement on the studied system according to the manual reading understanding. The trained technician collected capillary blood samples in microtainer tubes (with heparin anticoagulant) to be measured on the YSI 2300 Stat Plus Glucose Analyzer in duplicate.

Additionally, capillary blood samples were collected for the accuracy at extreme glucose values study. In this study, collected capillary blood samples are either glycolyzed or spiked with additional glucose for both YSI reference measurement and meter measurement.

Results relative to YSI:

Tested Glucose Concentration Range:

In the user evaluation study, reference glucose concentrations measured from YSI 2300 Stat Plus ranged from 53.8 to 537.5 mg/dL. 21 unaltered capillary samples were collected with glucose concentration <80 mg/dL, and 48 unaltered capillary samples were collected with glucose concentration >250 mg/dL. The subject blood hematocrit range was 26-58%.

Fingertip:

Summary of Linear Regression – Fingertip Site Measurement by Lay Users

Strip Lot		Slope	Intercept	R	R^2	N
1790001	Linear Regression	0.9988	-0.6583	0.9917	0.9836	122
	Lower 99% Confidence Interval	0.9680	-6.0381			
	Upper 99% Confidence Interval	1.0297	4.7214			

Strip Lot		Slope	Intercept	R	R^2	N
1790002	Linear Regression	1.0155	-3.1305	0.9914	0.9828	122
	Lower 99% Confidence Interval	0.9834	-9.0532			
	Upper 99% Confidence Interval	1.0475	2.7923			

Strip Lot		Slope	Intercept	R	R^2	N
1790003	Linear Regression	1.0245	-5.2398	0.9917	0.9834	122
	Lower 99% Confidence Interval	0.9927	-10.5395			
	Upper 99% Confidence Interval	1.0563	0.0600			

Strip Lot		Slope	Intercept	R	R^2	N
All 3 Lots	Linear Regression	1.0132	-3.0677	0.9915	0.9831	366
	Lower 99% Confidence Interval	0.9952	-6.2246			
	Upper 99% Confidence Interval	1.0312	0.0893			

Summary of User Evaluation System Accuracy in Tabular Format – Fingertip Site Measurement by Lay Users

Finger Site			
Lot 1790001			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
67 / 122 (54.9%)	109 / 122 (89.3%)	122 / 122 (100.0%)	122 / 122 (100.0%)

Finger Site			
Lot 1790002			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
68 / 122 (55.7%)	109 / 122 (89.3%)	121 / 122 (99.2%)	122 / 122 (100.0%)

Finger Site			
Lot 1790003			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
66 / 122 (54.1%)	107 / 122 (87.7%)	121 / 122 (99.2%)	122 / 122 (100.0%)

Finger Site			
All 3 Lots Combined			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
201 / 366 (54.9%)	325 / 366 (88.8%)	364 / 366 (99.5%)	366 / 366 (100.0%)

Summary of Linear Regression – Palm Site Measurement by Lay Users

Strip Lot		Slope	Intercept	R	R^2	N
1790001	Linear Regression	1.0003	-1.7710	0.9867	0.9735	122
	Lower 99% Confidence Interval	0.9609	-8.6405			
	Upper 99% Confidence Interval	1.0397	5.0984			

Strip Lot		Slope	Intercept	R	R^2	N
1790002	Linear Regression	0.9722	1.1633	0.9907	0.9816	122
	Lower 99% Confidence Interval	0.9404	-4.7125			
	Upper 99% Confidence Interval	1.0040	7.0392			

Strip Lot		Slope	Intercept	R	R^2	N
1790003	Linear Regression	0.9883	-1.6537	0.9890	0.9781	122
	Lower 99% Confidence Interval	0.9530	-7.5432			
	Upper 99% Confidence Interval	1.0237	4.2358			

Strip Lot		Slope	Intercept	R	R^2	N
All 3 Lots	Linear Regression	0.9851	-0.4936	0.9889	0.9780	366
	Lower 99% Confidence Interval	0.9650	-4.0130			
	Upper 99% Confidence Interval	1.0052	3.0259			

Summary of System Accuracy in Tabular Format – Palm Site Measurement by Lay Users

Palm Site			
Lot 1790001			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
63 / 122 (51.6%)	104 / 122 (85.2%)	121 / 122 (99.2%)	122 / 122 (100.0%)

Palm Site			
Lot 1790002			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
63 / 122 (51.6%)	103 / 122 (84.4%)	121 / 122 (99.2%)	122 / 122 (100.0%)

Palm Site			
Lot 1790003			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
62 / 122 (50.8%)	102 / 122 (83.6%)	120 / 122 (98.4%)	122 / 122 (100.0%)

Palm Site			
All 3 Lots Combined			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
188 / 366 (51.4%)	309 / 366 (84.4%)	362 / 366 (98.9%)	366 / 366 (100.0%)

Summary of Linear Regression – Forearm Site Measurement by Lay Users

Strip Lot		Slope	Intercept	R	R^2	N
1790001	Linear Regression	1.0086	-0.3791	0.9889	0.9779	122
	Lower 99% Confidence Interval	0.9724	-6.6891			
	Upper 99% Confidence Interval	1.0448	5.9308			

Strip Lot		Slope	Intercept	R	R^2	N
1790002	Linear Regression	0.9822	3.5869	0.9895	0.9791	122
	Lower 99% Confidence Interval	0.9480	-2.7368			
	Upper 99% Confidence Interval	1.0165	9.9106			

Strip Lot		Slope	Intercept	R	R^2	N
1790003	Linear Regression	0.9993	1.2168	0.9863	0.9728	122
	Lower 99% Confidence Interval	0.9593	-5.4384			
	Upper 99% Confidence Interval	1.0392	7.8721			

Strip Lot		Slope	Intercept	R	R^2	N
All 3 Lots	Linear Regression	0.9946	1.7728	0.9884	0.9770	366
	Lower 99% Confidence Interval	0.9739	-1.8616			
	Upper 99% Confidence Interval	1.0154	5.4071			

Summary of User Evaluation System Accuracy in Tabular Format – Forearm Site Measurement by Lay Users

Forearm Site			
Lot 1790001			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
61 / 122 (50.0%)	101 / 122 (82.8%)	120 / 122 (98.4%)	122 / 122 (100.0%)

Forearm Site			
Lot 1790002			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
59 / 122 (48.4%)	100 / 122 (82.0%)	119 / 122 (97.5%)	122 / 122 (100.0%)

Forearm Site			
Lot 1790003			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
60 / 122 (49.2%)	102 / 122 (83.6%)	120 / 122 (98.4%)	122 / 122 (100.0%)

Forearm Site			
All 3 Lots Combined			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
180 / 366 (49.2%)	303 / 366 (82.8%)	359 / 366 (98.1%)	366 / 366 (100.0%)

Part I Conclusion (User Evaluation Study)

The results of the study passed the acceptance criteria that 95% of all SMBG results are within 15% of the comparator results across the entire claimed measuring range of the device, and that 99% of all SMBG results are within 20% of the comparator results across the entire claimed measuring range for the device.

Part II:

Accuracy at Extreme Glucose Values Study

Based on "FDA Guidance for Industry and Food and Drug Administration Staff-Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use (2016)," the accuracy at the extreme upper and lower ends of the claimed measuring range were assessed using capillary blood samples obtained from subjects in the user evaluation study. Capillary blood samples (n=149) were saved and used for the accuracy at extreme glucose values study. 88 capillary blood samples were glycolyzed at room temperature to obtain glucose concentrations <80 mg/dL, and 61 capillary blood samples were spiked with glucose solution to obtain glucose concentrations >250 mg/dL. Each contrived blood sample was measured with the SMBG in duplicate for each lot.

Results relative to YSI:

Summary of Accuracy at Extreme Glucose Values Study – Tabular Data Format

Low Glucose Level: 40 - 80 mg/dL, First Measurement Only
Accuracy at Extreme Glucose Value by Absolute Bias - Low

On Call Sure/On Call Sure Sync BGMS - Accuracy at Extreme Glucose Values				
Glucose concentrations ⩽ 80 mg/dL				
Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
1790001	63 / 88 (71.6%)	88 / 88 (100.0%)	88 / 88 (100.0%)	88 / 88 (100.0%)
1790002	70 / 88 (79.5%)	88 / 88 (100.0%)	88 / 88 (100.0%)	88 / 88 (100.0%)
1790003	66 / 88 (75.0%)	88 / 88 (100.0%)	88 / 88 (100.0%)	88 / 88 (100.0%)
All 3 Lots	199 / 264 (75.4%)	264 / 264 (100.0%)	264 / 264 (100.0%)	264 / 264 (100.0%)

High Glucose Level: 250 - 600 mg/dL, First Measurement Only
Accuracy at Extreme Glucose Value by % Bias – High

On Call Sure/On Call Sure Sync BGMS - Accuracy at Extreme Glucose Values				
Glucose concentrations ⩾ 250 mg/dL				
Lot	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
1790001	43 / 61 (70.5%)	58 / 61 (95.1%)	61 / 61 (100.0%)	61 / 61 (100.0%)
1790002	40 / 61 (65.6%)	55 / 61 (90.2%)	61 / 61 (100.0%)	61 / 61 (100.0%)
1790003	41 / 61 (67.2%)	58 / 61 (95.1%)	61 / 61 (100.0%)	61 / 61 (100.0%)
All 3 Lots	124 / 183 (67.8%)	171 / 183 (93.4%)	183 / 183 (100.0%)	183 / 183 (100.0%)

Part II Conclusion (Accuracy at Extreme Glucose Values Study)

The results of the study passed the acceptance criteria that 95% of all SMBG results are within 15% of the comparator results across the entire claimed measuring range of the device, and that 99% of all SMBG results are with 20% of the comparator results across the entire claimed measuring range for the device.

Overall Conclusions:

The results of the study demonstrated that the On Call Sure Sync Blood Glucose Monitoring System is accurate in the claimed measuring range using finger capillary blood samples obtained from subjects, based upon both the user evaluation and the extreme glucose values study.