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

A. 510(k) Number:

k181527

B. Purpose for Submission:

New Device

C. Measurand:

Capillary Whole Blood Glucose

D. Type of Test:

Quantitative, Amperometric, Glucose Dehydrogenase (FAD-GDH)

E. Applicant:

ACON Laboratories, Inc.

F. Proprietary and Established Names:

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

G. Regulatory Information:

1. Regulation section:

   862.1345 Glucose Test System

2. Classification:

   Class II

3. Product code:

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

4. Panel:

   75, Chemistry

H. Intended Use:

1. Intended use(s):

   See Indications for use below.

2. Indication(s) for 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).

3. Special conditions for use statement(s):

   - For in-vitro diagnostic use only.

- For over-the-counter use.
- For testing capillary whole blood from finger, palm, and forearm only.
- Not for screening or diagnosis of diabetes.
- This system should not be used on critically ill patients.
- The system should not be used to test neonates.
- Not to be used for patients who are dehydrated, hypotensive, in shock, critically ill or in a hyperosmolar state.
- For single patient use only.
- Very high (above 70%) and very low (below 10%) hematocrit levels can cause false results. Talk to your doctor to find out your hematocrit level.
- Not for use at elevations over 10,000 ft (3,048 meters) above sea level.
- Alternative site testing should only be done during steady-state times (when glucose is not changing rapidly).
- Alternative site testing should not be used at times when blood glucose concentrations are changing rapidly.
- Alternative site measurements should never be used to calibrate continuous glucose monitoring systems (CGMs).
- Alternative site measurements should never be used for insulin dosing calculation.
- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.
- Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

4. Special instrument requirements:

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

I. Device Description:

The On Call Sure Blood Glucose Monitoring System and On Call Sure Sync Blood Glucose Monitoring System 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.

Both meters are equipped with USB data transfer functionality that activated upon validation with the On Call Diabetes Management Software (K131469). The On Call Sure Sync Blood Glucose Meter is also equipped with Bluetooth.

On Call Sure Glucose Control Solutions are available in three levels (Level 0, Level 1 and

Level 2). Level 1 is provided with the system. Level 0 and Level 2 are sold separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ACON Laboratories, Inc. On Call Sharp Blood Glucose Monitoring System

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

   k130284

3. Comparison with predicate:

	Similarities		
Item	On Call Sure Blood Glucose Monitoring System (Candidate)	On Call Sure Sync Blood Glucose Monitoring System (Candidate)	On Call Sharp Blood Glucose Monitoring System (Predicate)
Indications for use	The On Call Sure Blood Glucose Monitoring System and the On Call Sure Sync Blood Glucose Monitoring System are intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, forearm or palm. They are intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.	Same	Same
Detection Method	Amperometric electrochemical	Same	Same
Enzyme	Glucose Dehydrogenase (FAD-GDH)	Same	Same
Type	Capillary whole blood	Same	Same
Sample Sites	Fingertip, forearm, palm	Same	Same
Sample Test Time	5 seconds	Same	Same

	Differences		
Item	On Call Sure Blood Glucose Monitoring System (Candidate)	On Call Sure Sync Blood Glucose Monitoring System (Candidate)	On Call Sharp Blood Glucose Monitoring System (Predicate)
Calibration Coding	Auto-coding	Auto-coding	Non-coding
Test Range	40-600 mg/dL	40-600 mg/dL	20-600 mg/dL
Memory	1000 records with time and date	1000 records with time and date	500 records with time and date
Meter Size	90 x 60 x 16 mm	90 x 60 x 16 mm Auto-coding	88 x 49 x 17 mm
Meter Weight	Approx. 72 g (with batteries installed)	Approx. 72 g (with batteries installed) 40-600 mg/dL	Approx. 50 g (with battery installed)
Battery Life	Minimum of 3,000 measurements	Minimum of 3,000 measurements (Not considering Bluetooth data transfer)	Minimum of 1,000 tests
Wireless	None	2.4 GHz worldwide ISM (Instrumentation, Scientific, and Medical) band; Bluetooth 4.2 Low Energy	None

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

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter-Use, Guidance for Industry and Food and Drug Administration Staff. October 11, 2016.

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff. May 11, 2005.

General Principles of Software Validation - Final Guidance for Industry and FDA Staff CLSI EP6-A, 2014, Evaluation of the Linearity of Quantitative Measurement Procedures: A statistical Approach; Approved Guideline. January 11, 2002.

CLSI EP07-A2, 2005, Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition

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)

IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic Compatibility - Requirements and Tests

L. Test Principle:

The On Call Sure Sync and On Call Sure Sync Blood Glucose Monitoring Systems use electrochemical methodologies that use a reagent system that includes glucose dehydrogenase (FAD-GDH) and a mediator that reacts with the glucose in the whole blood sample obtained from the fingertip, forearm, and/or palm 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.

M. Performance Characteristics (if/when applicable):

The only differences between the On Call Sure and On Call Sure Sync Blood Glucose Monitoring Systems in this submission are the presence and absence of Bluetooth functionality and the device names. Therefore, the performance studies presented below were conducted using the On Call Sure Sync Blood Glucose Monitoring System as a representative device.

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor performed within-run precision studies using venous whole blood samples adjusted to six glucose concentration levels (30-50, 51-110, 111-150, 151-250, and 251-400, and 401-600 mg/dL). Each glucose level was analyzed in replicates of 10, with 3 test strip lots and 10 meters for a total of 300 measurements with each glucose concentration. Results are summarized below:

Venous Blood Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1 (30-50)	1	100	42.2	1.33	3.2
	2	100	42.8	1.22	2.8
	3	100	42.6	1.10	2.6
	Combined	300	42.6	1.24	2.9
Level 2 (51-110)	1	100	82.8	2.32	2.8
	2	100	82.1	2.21	2.7
	3	100	81.8	2.22	2.7
	Combined	300	82.2	2.23	2.8
Level 3 (111-150)	1	100	132.7	3.33	2.5
	2	100	134.7	3.39	2.5
	3	100	132.6	3.01	2.3

Venous Blood Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
	Combined	300	133.3	3.37	2.5
Level 4 (151-250)	1	100	204.2	4.48	2.2
	2	100	207.3	5.29	2.6
	3	100	204.0	4.63	2.3
	Combined	300	205.1	5.03	2.5
Level 5 (251-400)	1	100	331.3	7.25	2.2
	2	100	338.5	8.80	2.6
	3	100	334.0	8.20	2.5
	Combined	300	334.6	8.61	2.6
Level 6 (401 – 600)	1	100	517.3	10.51	2.0
	2	100	519.6	10.87	2.1
	3	100	515.8	13.06	2.5
	Combined	300	517.6	11.60	2.2

Intermediate (Day-to-day) precision was evaluated using six levels of control solutions with glucose concentration ranges of 30-50, 51-110, 111-150, 151-250, and 251-400, and 401-600 mg/dL. Each glucose level was measured in replicates of 10 with 3 test strip lots and 10 meters over 10 consecutive days for a total of 300 measurements with each glucose concentration. Results summarized below:

Control Solution Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1 (30-50)	1	100	36.0 the	0.91	2.5
	2	100	35.8	1.09	3.0
	3	100	36.0	1.05	2.9
	Combined	300	35.9	1.02	2.8
Level 2 (51-110)	1	100	67.7	1.50	2.2
	2	100	67.6	1.77	2.6
	3	100	67.6	1.57	2.3
	Combined	300	67.7	1.62	2.4
Level 3 (111-150)	1	100	128.1	2.90	2.3
	2	100	127.8	3.39	2.7
	3	100	127.5	3.43	2.7
	Combined	300	127.8	3.24	2.5
Level 4 (151-250)	1	100	167.5	3.22	1.9
	2	100	167.8	4.26	2.5
	3	100	168.4	3.71	2.2
	Combined	300	167.9	3.76	2.2
Level 5 (251-400)	1	100	321.0	6.82	2.1
	2	100	320.9	6.32	2.0
	3	100	319.9	5.10	1.6
	Combined	300	320.6	6.12	1.9
Level 6	1	100	432.2	9.75	2.3

Control Solution Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
(401 – 600)	2	100	426.5	8.02	1.9
	3	100	420.7	7.61	1.8
	Combined	300	426.5	9.70	2.3

b. Linearity/assay reportable range:

For evaluation of linearity, venous whole blood was prepare at 11 glucose levels (9.8, 28, 54.5, 81.8, 111.8, 173.5, 227.4, 342, 444.8, 563.8, and 673.4 mg/dL as measured on the comparator method YSI 2300 STAT PLUS). Each glucose level was measured in replicates of 10 using each of 3 lots of test strips. Linear regression analysis for each test strip lot was compared to the plasma YSI. The evaluation yielded the following regression equations:

Lot	Slope	y-intercept	R^2
1	1.005	0.3755	0.9976
2	1.0023	-0.3007	0.9976
3	0.9948	0.4345	0.9991
Combined	1.0009	0.1698	0.9981

The results of the study support the sponsor's claimed glucose measurement range of 40 - 600 mg/dL. If a sample result is less than 40 mg/dL glucose, the result is flagged by the meter as "Lo". If a sample result exceeds 600 mg/dL glucose, the result is flagged by the meter as "Hi". The "Lo" and "Hi" functions were validated by the sponsor and were demonstrated to function as intended.

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

Traceability:

The On Call Sure Blood Glucose Monitoring System and On Call Sure Sync Blood Glucose Monitoring System are traceable to the NIST SRM 917b reference material.

Test Strip Stability:

Stability of the On Call Sure Blood Glucose Test Strips was assessed using real time and accelerated studies. Protocols and acceptance criteria were reviewed and found to be acceptable. The sponsor claims shelf life stability of 24 months and open-vial stability of 6 months when stored at the recommended storage conditions of 36°F-95°F (2-35°C) and 10-90% relative humidity (RH).

d. Detection limit:

See linearity study (Section M.1.b.) above.

e. *Analytical specificity:*

For the evaluation of interference, 38 potentially interfering substances were spiked into venous whole blood. Each potentially interfering substance was tested at 3 glucose levels (50-70 mg/dL, 110-130 mg/dL and 250-270 mg/dL). Test samples were prepared to the specified concentration for each substance. Control samples were prepared without the potential interferent. Control and test samples were each measured in replicates of 30 and the bias between control and test samples was calculated. The highest interferent concentrations at which measurement bias was ≤10 mg/dL (for glucose <75 mg/dL) or ≤10% (for glucose ≥75 mg/dL) vs. control specimens is presented in the table below.

Substance	Highest concentration with no significant interference (mg/dL)
Acetaminophen	20
Ascorbic Acid	3
Cholesterol	500
Conjugated-Bilirubin	50
Creatinine	10
Dopamine	20
EDTA	200
Ephedrine	0.5
Ethanol	400
Fructose	100
Galatitol	0.09
Galactose	100
Gentisic acid	100
Glutathione (Reduced)	92
Hemoglobin	2000
Heparin Sodium	80000
Ibuprofen	50
Isomalt	0.09
Lactitol	0.09
Lactose	25
L-Dopa(Levo-Dopa)	3
Maltitol	0.09
Maltose	10000
Mannitol	600
Methyl Dopa	1000
Paralidoxime Iodide (PAM)	80
Salicylic Acid	60
Sodium	414
Sorbitol	70

Tetracycline	1.5
Tolazamide	40
Tolbutamide	100
Triglycerides	3000
Unconjugated-Bilirubin	40
Urea	600
Uric Acid	24
Xylitol	0.09
Xylose	6

The sponsor has added the following statements to their labeling:

If you are taking a high dose of vitamin C (blood concentration > 3 mg/dL), the result from your meter may not be correct.

Do not use during or soon after xylose absorption testing since xylose may cause inaccurate glucose results. Ask your doctor how long to wait before performing a glucose test.

f. Assay cut-off:

Not applicable.

a. Comparison studies:

b. Method comparison with predicate device:

See lay user study below in section M.3.c.

b. Matrix comparison :

Not applicable.

2. Clinical studies:

c. Clinical Sensitivity:

Not applicable

d. *Clinical specificity:*

Not applicable

e. Other clinical supportive data (when a. and b. are not applicable):

User Evaluation Study

To assess the performance of the On Call Sure/On Call Sure Sync Blood Glucose Monitoring System in the hands of intended users, the sponsor conducted a user evaluation study consisting of 366 participants who collected capillary samples from their fingertip, palm, and forearm on their own and obtained blood glucose measurements on the candidate device using only the On Call Sure/On Call Sure Sync Blood Glucose Monitoring System labeling. Three test strip lots were used for this study and results were analyzed against results obtained on the comparator method, the YSI 2300 STAT PLUS analyzer. The glucose concentrations of the samples ranged from 53.8-537.5 mg/dL as measured on YSI 2300 Stat Plus (21 unaltered samples contained glucose <80 mg/dL and 48 unaltered samples contained glucose >250 mg/dL). Results are summarized below:

For Glucose Concentrations <75 mg/dL

	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	Within ±20 mg/dL
Fingertip	10/11 (90.9%)	11/11 (100%)	11/11 (100%)	11/11 (100%)
Palm	8/11 (72.7%)	11/11 (100%)	11/11 (100%)	11/11 (100%)
Forearm	5/11 (45.5%)	10/11 (90.9%)	11/11 (100%)	11/11 (100%)

For Glucose Concentrations ≥75 mg/dL

	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Fingertip	196/355 (55.2%)	315/355 (88.7%)	353/355 (99.4%)	355/355 (100%)
Palm	182/355 (51.3%)	301/355 (84.8%)	351/355 (98.9%)	355/355 (100%)
Forearm	176/355 (49.6%)	297/355 (83.7%)	349/355 (98.3%)	355/355 (100%)

Analysis of all glucose concentrations combined

	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Fingertip	201/366 (54.9%)	325/366 (88.8%)	364/366 (99.5%)	366/366 (100.0%)
Palm	188/366 (51.4%)	309/366 (84.4%)	362/366 (98.9%)	366/366 (100.0%)
Forearm	180/366 (49.2%)	303/366 (82.8%)	359/366 (98.1%)	366/366 (100.0%)

Linear Regression Analysis:

	Fingertip	Palm	Forearm
Slope	1.0132	0.9851	0.9946
Y-intercept	-3.0677	-0.4936	1.7728
R^2	0.9915	0.9889	0.9884

Usability/ Readability Study

A readability study was conducted on the proposed user's manuals, quick reference guide, quick start guide, and test strip package insert. The results of the readability study indicated a Flesch-Kincaid Score of 8 and lower for all instructional materials included with this device.

Extreme Glucose Study

System performance at the extreme upper (>250 mg/dL) and lower (<80 mg/dL) ends of the claimed device measuring range was further assessed using additional capillary blood collected from 149 participants. Following collection, extreme glucose study samples were glycolyzed or spiked to obtain 88 samples with glucose concentrations <80 mg/dL and 61 samples >250 mg/dL. Each sample was measured using the On Call Sure System and results compared those obtained using the YSI comparator method. Results are summarized in the tables below:

Glucose concentrations ≤ 80 mg/dL

Within 5mg/dL	Within ±10mg/dL	Within ±15mg/dL	Within ±20mg/dL
63/88 (71.6%)	88/88 (100%)	88/88 (100%)	88/88 (100%)

Glucose concentrations ≥ 250 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
43/61 (70.5%)	58/61 (95.1%)	61/61 (100%)	61/61 (100%)

3. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:

Expected blood glucose levels for people without diabetes.

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

Source: American Diabetes Association (Standards of Medical Care in Diabetes – 2018. Diabetes Care, January 2018, vol. 41, Supplement 1, S13-S27).

N. Instrument Name:

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

O. System Descriptions:

1. Modes of Operation:

   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?

   On Call Sure Sync Blood Glucose Monitoring System is equipped with Bluetooth.
   Yes ____X____ or No _____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ____X____ or No _____

4. 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 finger, palm, and forearm. The whole blood sample is applied directly to the test strip, so there are no special handling considerations.

5. Calibration:

   No user calibration is required.

6. Quality Control:

   The On Call Sure Glucose Control Solutions are used to confirm that the meter and test strips are working properly. Glucose control solutions are viscosity-adjusted, buffered aqueous control solutions that contain known concentrations of d-glucose. Three solution levels are available (Level 0, Level 1 and Level 2) for use with the systems. Level 1 is provided with the system kit. Level 0 and Level 2 are sold separately. Instructions on how to order the control solutions are included in the user manual. The meter automatically detects control solution readings. 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. Hematocrit: To evaluate the effect of hematocrit on the On Call Sure/Sure Sync Blood Glucose Monitoring System, venous blood samples were adjusted to hematocrit levels of 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65% and 70%. Each hematocrit level was tested at six glucose concentration intervals (~40, ~80, ~130, ~200, ~325, and ~500 mg/dL). Each sample was tested in replicates of ten using 30 meters and 3 test strip lots. Results from the meter were compared to results obtained using a laboratory-based comparator measurement (YSI 2300 STAT PLUS analyzer). The evaluation of bias and percent bias relative to values obtained on the YSI 2300 STAT PLUS analyzer support the claimed hematocrit range of 10-70%.

2. Altitude: To evaluate the effect of altitude on the On Call Sure/Sure Sync Blood Glucose Monitoring System, meters were tested at 16 ft and 10,790 ft on fingerstick capillary blood acquired from 22 subjects at each altitude. Each sample was tested with 2 test strips from each of 3 strip lots on 2 meters. Results were compared to results obtained for venous plasma samples on laboratory-based comparator measurements taken at each altitude (i.e., at sea level YSI 2300 STAT PLUS analyzer was used and at 10,000 ft Beckman Coulter UniCel DxC 800 Synchron Clinical System was used). At sea level, the reference glucose concentration range was 74.4 – 406.6 mg/dL (33 – 52% hematocrit). At 10,000 ft, the reference glucose concentration range was 59.4 – 282.6 mg/dL (39 – 61% hematocrit). Test results support the claims in the labeling that altitudes of up to 10,000 feet have no significant effect on performance of the On Call Sure and On Call Sure Sync systems.

3. Operating Conditions: To evaluate system performance under the extremes of the recommended temperature and humidity conditions, venous samples were prepared at six glucose concentration levels (45.2, 103.0, 130.7, 202.4, 327.0, and 526.6 mg/dL). Test strips from 3 lots were exposed to one of 7 relative humidity (RH) and temperature conditions (10% RH/5ºC, 10% RH/21ºC, 10% RH/45ºC, 90% RH/5ºC, 90% RH/21ºC, 90% RH/45ºC, or 45% RH/21ºC). The results from the On Call Sure system were compared to results obtained using the comparator method, YSI 2300 STAT PLUS, and support the claimed operating conditions of 10-90% RH and 41-113ºF (5-45ºC).

4. Sample Volume: To verify the minimum sample volume requirement, venous whole blood samples were tested at five volumes (0.4, 0.5, 0.6, 0.7, and 0.8 µL). Sample concentrations included three glucose levels (50-65, 100-120, and 200-250 mg/dL). Values obtained with the candidate device were compared to values obtained using the comparator method (YSI 2300 STAT PLUS analyzer). Results support the claimed minimum sample volume of 0.6 µL. The sponsor provided validation studies demonstrating that with blood volumes below 0.6 µL, the insufficient sample volume

error message functioned as intended.

5. Sample Perturbation: The sponsor demonstrated that, while an error code (E-5: Insufficient sample volume error) was triggered when sample was removed during measurement, perturbation via shaking the meter and test strip, hitting the meter, or flicking the test strip during measurement does not significantly affect meter glucose results.

6. Intermittent Sampling: The sponsor demonstrated that intermittent sample application triggers an error code (E-5) when a short sample is initially applied to the test strip followed by a second sample application to the test strip. The results demonstrated that the device does not provide blood glucose values when samples are intermittently applied. The labeling indicates that the user should apply enough sample to fill the test strip check window within 3 seconds.

7. Testing with Used Test Strips: The sponsor demonstrated that used test strips were accurately detected by the meters when samples were applied to test strips prior to insertion into the meter and when previously used test strips were re-inserted in the meter after drying.

8. A variety of mechanical/durability testing (i.e., drop testing, temperature exposure, humidity exposure, temperature sensitivity and limit testing, test strip connector durability, vibration, packaging, and battery life testing) was performed and the ACON On Call Sure/Sure Sync Blood Glucose Monitoring System to demonstrate that the meter is robust to environmental and mechanical stresses.

9. Infection Control and Robustness Studies: The ACON On Call Sure/Sure Sync Blood Glucose Monitoring System is intended for single-patient use. Disinfection efficacy testing on the surface materials of the meter demonstrated complete inactivation of duck hepatitis B virus (HBV) with the chosen disinfectants, DisCide Ultra Disinfecting Towelettes (EPA Registration #10492-4) and PDI Super Sani-Cloth Germicidal Disposal Wipes (EPA Registration #9480-4). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 260 cleaning and disinfection cycles (a total of 520 wipes) designed to simulate 5 years of single-patient use for the ACON On Call Sure/Sure Sync Blood Glucose Monitoring System. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

10. The sponsor provided documentation certifying that acceptable electromagnetic (EMC) testing was performed and the ACON On Call Sure/Sure Sync Blood Glucose Monitoring System were found to be compliant.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.