



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

I Background Information:

A 510(k) Number

K250085

B Applicant

ACON Laboratories, Inc.

C Proprietary and Established Names

On Call® Sure GK Blood Glucose & Ketone Monitoring System

On Call® Sure Sync GK Blood Glucose & Ketone Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry
JIN	Class I	21 CFR 862.1435 - Ketones (nonquantitative) test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification to add a blood ketone measurement functionality to previously cleared blood glucose monitoring systems (k181527).

B Measurand:

Glucose and β -hydroxybutyrate in capillary whole blood obtained from the fingertip.

C Type of Test:

Quantitative amperometry assays for glucose (glucose dehydrogenase-FAD) and β -hydroxybutyrate (3-hydroxybutyrate dehydrogenase).

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The On Call® Sure GK Blood Glucose & Ketone Monitoring System is comprised of the On Call® Sure GK Blood Glucose & Ketone Meter, the On Call® Sure Blood Glucose Test Strips, and the On Call® Sure Blood Ketone Test Strips.

The On Call® Sure GK Blood Glucose & Ketone Monitoring System is intended to quantitatively measure blood glucose or blood ketone in fresh capillary whole blood from the fingertip. The system is intended for self-testing by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control program. The system is for in vitro diagnostic use. It should only be used by a single patient and should not be shared. It is not intended for diagnosis or screening of diabetes or for neonatal use.

The On Call® Sure Syn GK Blood Glucose & Ketone Monitoring System is comprised of the On Call® Sure Syn GK Blood Glucose & Ketone Meter, the On Call® Sure Blood Glucose Test Strips, and the On Call® Sure Blood Ketone Test Strips.

The On Call® Sure Syn GK Blood Glucose & Ketone Monitoring System is intended to quantitatively measure blood glucose or blood ketone in fresh capillary whole blood from the fingertip. The system is intended for self-testing by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control program. The system is for in vitro diagnostic use. It should only be used by a single patient and should not be shared. It is not intended for diagnosis or screening of diabetes or for neonatal use.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

- Not for use with alternative site testing.
- Only for testing capillary whole blood from the finger.
- Not for screening for 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 severely dehydrated, have very low blood pressure, are in shock, or in hyperglycemic-hyperosmolar state.
- If you are taking high level of vitamin C (ascorbic acid levels in your blood > 3mg/dL), your test results may not be reliable. If you are unsure, ask your doctor.

- Not to be used for patients who are severely dehydrated, have very low blood pressure, are in shock, or in a hyperglycemic-hyperosmolar state.
- Do not use during or soon after xylose absorption testing since xylose may cause inaccurate glucose results. Ask a healthcare professional how long to wait before performing a glucose test.
- Not for use at elevations over 10,000 ft (3,048 meters) above sea level.
- For single patient use only.
- This device is not intended for use in healthcare or assisted use settings such as hospitals, physician offices, or long-term 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 may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

D Special Instrument Requirements:

On Call® Sure GK meter
On Call® Sure Sync GK meter

IV Device/System Characteristics:

A Device Description:

The On Call® Sure GK Blood Glucose and Ketone Monitoring System and the On Call® Sure Sync GK Blood Glucose and Ketone Monitoring System share the same device technology and the same intended use. Each of the device systems is comprised of an On Call® Sure GK Blood Glucose and Ketone Meter (Sure GK or Sure Sync GK), the On Call® Sure Blood Glucose Test Strips, and the On Call® Sure Blood Ketone Test Strips. The On Call® Sure Blood Glucose, On Call® Sure Blood Ketone Test Strips Ketone Test Strips as well as the On Call® Sure Glucose Control Solutions (levels 0, 1 and 2), On Call® Sure Ketone Control Solutions (levels 0, 1 and 2), lancing device and sterile lancets can be purchased separately for use with the systems. The test strips can be purchased in vials or individually wrapped foil packages. A user's manual, test strip inserts, quick reference guide, quick start guide, warranty card, logbook and carrying case are provided with the system components. The systems differ only in name and in the data transmission function. The On Call® Sure Sync GK Blood Glucose and Ketone meter contains an additional Bluetooth module to transmit glucose and ketone readings wirelessly to mobile devices.

B Principle of Operation:

The meters and test strips use amperometric biosensor technology for the detection of glucose and β -hydroxybutyrate (ketones) in fresh capillary fingerstick whole blood. The blood sample is pulled into the tip of the test strips through capillary action. The glucose test strip contains the enzyme glucose dehydrogenase (FDA-GDH) and a mediator that reacts with glucose in the sample to produce an electrical current. The ketone test strip contains the enzyme 3-hydroxybutyrate dehydrogenase and a mediator that reacts with the ketones in the sample to

produce an electrical current signal. The meters measure the current generated that correlates to the glucose or ketone concentration in the blood samples. The system is calibrated to display plasma equivalent results (in mg/dL for glucose and mmol/L for ketones) on the meter for the user.

C Instrument Description Information:

1. Instrument Name:

The On Call® Sure GK Blood Glucose and Ketone Meter
The On Call® Sure Sync GK Blood Glucose and Ketone Meter

2. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

3. Specimen Sampling and Handling:

Samples are to be tested immediately upon collection.

4. Calibration:

The meters do not require calibration or coding by the user. The meters are automatically coded.

5. Quality Control:

Three (3) levels of On Call® Sure Glucose Control Solutions (Level 0, Level 1, Level 2) and three (3) levels of On Call® Sure Ketone Control Solutions (Level 0, Level 1, Level 2) are available to use with the test systems. Recommendations on when to test the control solutions are provided in the labeling. Acceptable ranges for each control solution level are printed on the test strip vial label. If quality control test results are out of range, the user is instructed to repeat the test. If the problem continues, the user is instructed to stop using the meter and to contact customer support.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Substantial Equivalence Information:

A Predicate Device Name(s):

MultiSure GK Link Blood Glucose and Ketone Monitoring System

B Predicate 510(k) Number(s):

k201880

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K250085</u>	<u>K250085</u>	<u>K201880</u>
Device Trade Name	On Call® Sure GK Blood Glucose and Ketone Monitoring System	On Call® Sure Sync GK Blood Glucose and Ketone Monitoring System	MultiSure GK Link Blood Glucose and Ketone Monitoring System
General Device Characteristic Similarities			
Intended Use/Indications For Use	For the quantitative measurement of glucose and β -ketone in fresh capillary whole blood from the fingertip as an aid in the monitoring the effectiveness of diabetes control program.	Same	Same
Ketone Measuring Range	0.1-8.0 mmol/L	Same	Same
Ketone Test Strips Active reagent	β -hydroxybutyrate dehydrogenase	Same	Same
General Device Characteristic Differences			
Hematocrit Range	10-70%	Same	20 – 60%
Data Transmission	USB	USB or Bluetooth	USB or Bluetooth

VI Standards/Guidance Documents Referenced:

Clinical and Laboratory Standards Institute (CLSI) EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods.

CLSI EP07: Interference Testing in Clinical Chemistry; Approved Guideline – Third Edition

CLSI EP37: Supplemental Tables for Interference Testing in Clinical Chemistry; Approved Guideline – First Edition.

CLSI EP32R: Metrological Traceability and Its Implementation

ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices.

IEC 60601-1:2020 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance Consolidated Edition.

IEC 60601-1-2:2014+AMD1:2020 Medical Electrical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

IEC 60601-1-6:2020 Medical Electrical Equipment Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability Consolidated Edition

IEC 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

IEC 62304:2006+A1:2016 Medical Device Software – Software Life-cycle Processes Consolidated Edition.

IEC 62366-1:2015+A1:2020 Medical devices Part 1 - Application of usability engineering to medical devices.

US FDA Guidance Document: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use. Guidance for Industry and Food and Drug Administration Staff. Issued on September 29, 2020.

VII Performance Characteristics (if/when applicable):

The On Call® Sure Sync GK Blood Glucose and Ketone Monitoring System was used as a representative model for the performance evaluations below to support both the On Call® Sure GK Blood Glucose and Ketone Monitoring System and the On Call® Sure Sync GK Blood Glucose and Ketone Monitoring System. The only differences between the systems are the name and the presence of Bluetooth technology in the On Call® Sure Sync GK Blood Glucose and Ketone Monitoring System, which does not impact the glucose and ketone measurement.

A Analytical Performance:

1. Precision/Reproducibility:

The precision of the glucose monitoring systems was previously established in k181527.

Ketone Within-Run Precision (Repeatability)

Within-run precision studies were performed within a day using venous whole blood samples adjusted to five ketone concentrations (0.1-0.75, 0.75-1.5, 1.5-3.0, 3.0-4.5, and 4.5-8.0 mmol/L). Each ketone level was tested in replicates of 10 on 10 meters using 3 lots of test

strips for a total of 300 measurements per ketone concentration. Results are summarized below:

Ketone Level (mmol/L)	Lot	N	Mean (mmol/L)	SD (mmol/L)	CV (%)
0.1 – 0.75	1	100	0.38	0.037	9.6%
	2	100	0.39	0.038	9.8%
	3	100	0.39	0.035	8.9%
	Combined	300	0.39	0.036	9.4%
0.75 – 1.5	1	100	1.02	0.037	3.6%
	2	100	1.01	0.035	3.4%
	3	100	1.02	0.036	3.5%
	Combined	300	1.02	0.036	3.5%
1.5 – 3.0	1	100	2.26	0.068	3.0%
	2	100	2.25	0.069	3.1%
	3	100	2.27	0.075	3.3%
	Combined	300	2.26	0.071	3.1%
3.0 – 4.5	1	100	3.75	0.110	2.9%
	2	100	3.74	0.113	3.0%
	3	100	3.75	0.113	3.0%
	Combined	300	3.75	0.112	3.0%
4.5 – 8.0	1	100	6.79	0.188	2.8%
	2	100	6.68	0.180	2.7%
	3	100	6.72	0.184	2.7%
	Combined	300	6.73	0.189	2.8%

Ketone Intermediate Precision

Intermediate precision was evaluated for 10 days using five levels of control solutions with ketone concentrations (0.1-0.75, 0.75-1.5, 1.5-3.0, 3.0-4.5, and 4.5-8.0 mmol/L) using 10 meters and 3 test strip lots. Each ketone control level was tested once a day with each meter and each test strip lot for 10 days, for a total of 300 replicates per level. Results are summarized below:

Ketone Level (mmol/L)	Strip Lot	N	Mean (mmol/L)	SD (mmol/L)	%CV
0.1 – 0.75	1	100	0.41	0.034	8.2%
	2	100	0.42	0.039	9.2%
	3	100	0.44	0.050	11.2%
	Combined	300	0.42	0.043	10.2%
0.75 – 1.5	1	100	1.20	0.045	3.7%
	2	100	1.19	0.043	3.6%
	3	100	1.21	0.046	3.8%
	Combined	300	1.20	0.046	3.8%
1.5 – 3.0	1	100	2.30	0.077	3.3%
	2	100	2.31	0.077	3.3%

Ketone Level (mmol/L)	Strip Lot	N	Mean (mmol/L)	SD (mmol/L)	%CV
	3	100	2.33	0.075	3.2%
	Combined	300	2.31	0.077	3.3%
3.0 – 4.5	1	100	3.76	0.108	2.9%
	2	100	3.78	0.111	2.9%
	3	100	3.80	0.115	3.0%
	Combined	300	3.78	0.112	3.0%
4.5 – 8.0	1	100	5.74	0.149	2.6%
	2	100	5.70	0.168	2.9%
	3	100	5.82	0.156	2.7%
	Combined	300	5.76	0.165	2.9%

2. Linearity:

Linearity of the glucose monitoring systems was previously established in k181527.

Ketone

The linearity of the ketone monitoring systems was evaluated using eleven venous whole blood samples adjusted to the following β -hydroxybutyrate concentrations: 0.7, 0.47, 0.94, 1.27, 1.85, 2.96, 4.05, 5.18, 6.34, 7.35, and 8.22 mmol/L (as measured by the comparator). Ketone results obtained using the On Call® Sure Sync GK Blood Glucose and Ketone Monitoring System were compared to those obtained using the comparator. The summary of the linear regression analysis for each lot was as follow:

Lot #	Slope	Y-intercept	R ² value
Lot 1	1.0153	-0.0935	0.9989
Lot 2	1.0187	-0.0972	0.9989
Lot 3	1.0088	-0.0696	0.9994

The results of the study support the sponsor's claimed ketone measuring range of 0.1 to 8.0 mmol/L. If a sample result is less than 0.1 mmol/L, the result is flagged by the meter as "KETLO". If a sample result exceeds 8.0 mmol/L, the result is flagged by the meter as "KETHI". The "KETLO" and "KETHI" functions were validated by the sponsor and were demonstrated to function as intended.

3. Analytical Specificity/Interference:

Analytical specificity of the glucose monitoring systems was previously established in k181527.

Ketone

To assess potential interference with the ketone measurement function, studies were performed by spiking exogenous and endogenous substances into venous whole blood containing three ketone concentrations (0.6 mmol/L, 2.3 mmol/L, and 4.3 mmol/L). Each of these samples was divided into a test pool and a control pool, with the potential interference

substances added to the test pool. Each sample was tested in replicates of 10 for each 3 test strip lots. The difference between the mean of the test sample (with interferent) as measured on the candidate device and the mean of the control sample (without interferent) as measured on the candidate device were calculated. The highest tested concentration for each substance at which no significant interference was observed (defined by the sponsor as within ± 0.15 mmol/L for β -ketone < 1.5 mmol/L and within $\pm 10\%$ for β -ketone ≥ 1.5 mmol/L) is summarized in the following table:

Test Substance	Highest concentration tested with no significant interference
Acetaminophen	20 mg/dL
Acetone	100 mg/dL
Acetoacetate	20 mg/dL
Ascorbic acid	3 mg/dL
Bilirubin (unconjugated)	40 mg/dL
Bilirubin (conjugated)	50 mg/dL
Captopril	15 mg/dL
Cholesterol	500 mg/dL
Creatinine	15 mg/dL
Dopamine	20 mg/dL
EDTA	200 mg/dL
Ephedrine	0.9 mg/dL
Ethanol	600 mg/dL
Fructose	100 mg/dL
Galactose	100 mg/dL
Galatitol	0.09 mg/dL
Gentisic acid	100 mg/dL
Glucose	900 mg/dL
Glutathione (Reduced)	92 mg/dL
Hemoglobin	2000 mg/dL
Heparin Sodium	80000 U/L
Ibuprofen	50 mg/dL
Isomalt	0.09 mg/dL
Lactitol	0.09 mg/dL
Lactose	25 mg/dL
L-DOPA (Levo-Dopa)	3 mg/dL
Maltitol	0.09 mg/dL
Maltose	1000 mg/dL

Test Substance	Highest concentration tested with no significant interference
Mannitol	1500 mg/dL
Methyl dopa	100 mg/dL
N-acetylcysteine	30 mg/dL
Paralidoxime Idodine (PAM)	80 mg/dL
Salicylic acid	60 mg/dL
Sodium	180 mmol/L
Sorbitol	70 mg/dL
Tolazamide	40 mg/dL
Tolbutamide	100 mg/dL
Triglyceride	3000 mg/dL
Urea	600 mg/dL
Uric acid	23.5 mg/dL
Xylitol	0.09 mg/dL
Xylose	600 mg/dL

The sponsor includes the following limitations in the labeling:

- Abnormally high levels of Vitamin C If you are taking a high level of vitamin C (ascorbic acid level in your blood > 3 mg/dL), your test results may not be reliable. If you are unsure, ask your doctor.
- Do not use during or soon after xylose absorption testing since xylose may cause inaccurate glucose tests. Ask a healthcare professional how long to wait before performing a glucose test.

4. Assay Reportable Range:

Glucose: 40 – 600 mg/dL

Ketone: 0.1 – 8.0 mmol/L

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability

Glucose traceability was reviewed in k181527.

The ketone monitoring systems report plasma-equivalent ketone values. The systems are traceable to commercially available calibrator materials from Randox using the Randox Ranbut D-3-Hydroxybutyrate assay.

Stability

Shelf-life and open vial stability protocols for the On Call® Sure Blood Glucose Test Strips were previously reviewed and found acceptable to support the labeling claims in k181527.

Test strip stability for the On Call® Sure Blood Ketone Test Strips were evaluated using real-time and accelerated studies. Study protocols and acceptance criteria were reviewed and found to be acceptable to support the shelf life stability claims (for vials and individually wrapped test strips) of 24 months and open-vial stability of 6 months when stored at the recommended storage conditions of 36°F and 86°F (2-30°C) and 10 to 90% relative humidity (RH).

6. Detection Limit:

See section VII.A.2 above.

7. Assay Cut-Off:

Not Applicable.

8. Accuracy (Instrument):

Not Applicable.

9. Carry-Over:

Not Applicable. The device uses single-use strips.

B Comparison Studies:

1. Method Comparison with Predicate Device:

See section VII.3 C below for accuracy in the hands of the intended user.

2. Matrix Comparison:

Not applicable. The device is only intended for use with fresh capillary whole blood from a fingerstick.

C Clinical Studies:

1. Clinical Sensitivity:

Not Applicable.

2. Clinical Specificity:

Not Applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Glucose:

The performance of the glucose monitoring systems in the hands of the intended users was previously established in k181527.

Ketone:

To assess the performance of the ketone monitoring system in the hands of the intended users, the sponsor conducted a lay user evaluation consisting of 101 participants who collected their own capillary fingerstick sample and obtained their ketone result using only system components and instructions provided in the labeling. The ketone concentrations of the samples ranged from 0.01 to 2.04 mmol/L. The results relative to the comparator are summarized below:

System accuracy results for samples with β -ketone concentration <1.5 mmol/L:

Within ± 0.15 mmol/L	Within ± 0.225 mmol/L	Within ± 0.30 mmol/L
86/97 (88.7%)	95/97 (97.9%)	97/97 (100%)

System accuracy results for samples with β -ketone concentration ≥ 1.5 mmol/L:

Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
4/4 (100%)	4/4 (100%)	4/4 (100%)

Linear regression analysis: $y=0.9753x + 0.0296$, $R^2=0.998$

A supplemental study with 53 altered whole blood samples was also performed to evaluate the accuracy performance at the extreme ketone concentrations. The data was found acceptable to support the claimed measuring range of up to 8 mmol/L.

Usability Assessment

The usability of the system was assessed by questionnaires given to the study participants following the conclusion of lay user evaluation where the study participants were asked to complete a questionnaire regarding ease of understanding of information in the user manual and the ease of use when performing a blood ketone test. From the sponsor's analysis of the questionnaire responses, the participants overall were satisfied with the ease of operation by following the instructions for use and the overall performance of ketone monitoring system

Readability Evaluation

The readability of the over-the-counter, home use labeling was evaluated using a Flesch-Kincaid analysis and demonstrated that the labeling documents meet the readability level of grade 8 or lower.

D Clinical Cut-Off:

Not Applicable.

E Expected Values/Reference Range:

Glucose

The reference range for glucose test was reviewed in k181527.

Ketone

The sponsor includes the following in the labeling: The normal adult blood β -ketone range for person without diabetes is less than 0.6 mmol/L. Consult with your healthcare professional for the blood β -ketone range that is appropriate for you

Source: Evans K. Diabetic ketoacidosis: update on management. Clin Med (Lond). 2019 Sep; 19 (5): 396-398.

F Other Supportive Instrument Performance Characteristics Data:

Hematocrit Effect

The impact of varying hematocrit levels on the glucose monitoring systems was previously established in k181527.

The effects of varying hematocrit levels on the ketone monitoring systems was evaluated using venous whole blood samples with varying hematocrit levels (10%, 15%, 20%, 25%, 30%, 35%, 42%, 50%, 55%, 60%, 65% and 70%) and five ketone concentrations (0.1-0.75, 0.75-1.5, 1.5-3.0, 3.0-4.5, 4.5-8.0 mmol/L). Each sample was tested in replicates of 10 using ten meters and three test strip lots. The % bias at each hematocrit level relative to the results at 42% hematocrit was calculated. The result support the claimed hematocrit range of 10 – 70%.

Operating Conditions Study

Operating conditions of the glucose monitoring systems was previously established in k181527.

The sponsor performed operating condition studies to evaluate the operating temperature and relative humidity (RH) ranges for the ketone monitoring systems. Venous whole blood samples were adjusted to four ketone concentration levels (0.2-1.0, 1.5-3.0, 3.5-5.0, 5.5-8.0 mmol/L) and tested under extreme temperature and humidity combinations (high temperature/high humidity 40°C/90%, high temperature/low humidity 40°C/10%, low temperature/high humidity 5°C/90%, and low temperature/low humidity 5°C/10%). The results obtained were compared to those obtained under nominal conditions (23°C/35-45%). The results support the claimed operating conditions for the system of 41- 104°F (5°C – 40°C) and 10-90% relative humidity.

Sample volume

The minimum sample volume for the glucose monitoring systems was previously established in k181527.

A sample volume study was conducted to verify the minimum sample volume required for the ketone monitoring systems. Venous whole blood samples with varying ketone concentrations (0.2 - 1.0, 1.5 - 3.0, 3.5 - 5.0 mmol/L) were tested at 0.6 μ L, 0.8 μ L, 1.0 μ L and 1.2 μ L sample volume. Samples had. Testing was performed using 10 test strips for each of three lots of test strips for each test volume and each ketone level. The meter displayed an insufficient sample

volume message when sample volume was <1.0 µL for all β-ketone concentrations range in the study. Results from the study support the claimed minimum sample volume of 1.0 µL.

Flex Studies:

The robustness of the glucose monitoring systems to expected use conditions was previously established in k181527. The following flex studies were performed with the ketone monitoring systems of the candidate systems: used test strip insertion, test strip removal during measurement, intermittent sampling, sample perturbation, and a variety of mechanical/durability testing (extreme temperature, low battery, simulated shipping study). The results demonstrated that the ketone monitoring systems are robust to these use scenarios and that either an error message is returned, or an accurate result is displayed.

EMC and Electrical Safety

The sponsor provided documentation certifying that acceptable electrical safety and (EMC) testing had been performed. The On Call® Sure GK Blood Glucose and Ketone Monitoring System and On Call® Sure Sync GK Blood Glucose and Ketone Monitoring System were found to be compliant.

Software and Cybersecurity

The sponsor provided software and cybersecurity documentation that was reviewed and found to be acceptable.

Infection Control Testing

The device systems are intended for single-patient use only. Disinfection efficacy studies were performed on the external meter materials by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, DisCide Ultra Disinfecting Towelette (EPA Registration #10492-4) or PDI Super Sani-Cloth Germicidal Wipe (EPA Reg. No. 9480-4). A robustness study was also conducted by the sponsor demonstrating that there was no change in performance nor in the external materials of the meter after 260 cleaning and disinfection cycles using the DisCide Ultra Disinfecting Towelette (EPA Registration #10492-4) or PDI Super Sani-Cloth Germicidal Wipe (EPA Reg. No. 9480-4). The robustness studies were designed to simulate 5 years of single-patient device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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