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

I Background Information:

A 510(k) Number

K201880

B Applicant

Apex Biotechnology Corp.

C Proprietary and Established Names

MultiSure GK Link Blood Glucose and 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, meets the limitation of exemption 21 CFR 862.9(c)(5)	21 CFR 862.1435 - Ketones (nonquantitative) test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Addition a blood ketone measurement functionality to a previously cleared blood glucose monitoring system (k170267) in a new meter shell.

B Measurand:

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

C Type of Test:

Quantitative, amperometry for glucose and β-hydroxybutyrate

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

MultiSure GK Link Blood Glucose and Ketone Monitoring System is comprised of the MultiSure GK Blood Glucose and Ketone Meter, the MultiSure GK Blood Glucose Test Strips, and the MultiSure GK Blood Ketone test strips.

The MultiSure GK Linle Blood Glucose and Ketone Monitoring System is intended to quantitatively measure blood glucose or blood ketone in fresh capillary whole blood drawn from fingertips. The system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control and should only be used by a single patient and it 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

- 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.
- Inaccurate results may occur in severely hypotensive individuals, patients in shock, in a hyperglycemic-hyperosmolar state with or without ketosis
- Do not use on critically ill patients.
- Do not use on neonates.
- Do not use the system above 10,335 feet (3,150 meters) in altitude.
- Do not use if hematocrit exceeds the acceptable range between 20% to 60%. when testing.
- Severe dehydration (excessive water loss) may cause inaccurate results.
- For single-patient use only.

D Special Instrument Requirements:

MultiSure GK Link Blood Glucose and Ketone Meter

IV Device/System Characteristics:

A Device Description:

The MultiSure GK Link Blood Glucose and Ketone Monitoring System consists of the MultiSure GK Link Blood Glucose and Ketone Meter, MultiSure GK Blood Glucose test strips, MultiSure GK Blood Ketone test strips, Contrex Plus 4 Glucose Control Solution (Level 1, Level 2 and Level 3), and KET-1 ketone control solution (Level 1 and Level 2). The MultiSure GK Blood Glucose test strips, MultiSure GK Blood Ketone test strips, Contrex Plus 4 Glucose Control Solution, and KET-1 ketone control solution can be purchased separately.

MultiSure GK Link Blood Glucose and Ketone Monitoring System enables automatic transmission of stored data from the meter to a mobile device via USB cable (optional), or through Bluetooth when the meter is properly configured.

B Principle of Operation:

The system uses amperometric technology for the detection of glucose and β-ketones. The glucose test strips contain an enzyme (glucose oxidase) that reacts to glucose present in blood, releasing electrons. The ketone test strips contain an enzyme (D-3-hydroxybutyrate dehydrogenase) that reacts with ketones present in blood, releasing electrons. The meter applies a small electrical current to the test strip and measures changes in the current caused by the reaction of glucose or ketone in the blood sample to the enzyme in the test strip. The meter converts the measured current into blood glucose or ketone reading that is displayed on the meter's display. Both the glucose and ketone test strips are plasma calibrated.

C Instrument Description Information:

1. Instrument Name:
   MultiSure GK Link 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 meter does not require calibration or coding by the user. The meter is automatically coded.

5. Quality Control:
   The sponsor manufactures three (3) levels of Contrex Plus 4 Glucose Control Solutions and (2) levels of KET-1 ketone control solutions. Each test strip vial includes a control solution range for each level. The user is instructed to compare the control results with the expected control ranges printed on the strip vial. Users are given instructions on when to conduct control solution testing and to call customer service if repeat testing with control material is

out of range. The user is instructed to switch the meter manually to control testing mode prior to the application of control solutions to allow for control solution results to be marked with "ctl" when stored in the meter's memory and not be included in the result averages.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Nova Max Plus Blood Glucose and B-ketone Monitor System

B Predicate 510(k) Number(s):

K091547

C Comparison with Predicate(s):

Device & Predicate Device(s):	K201880	K091547
Device Trade Name	MultiSure GK Link Blood Glucose and Ketone Monitoring System	Nova Max Plus Blood Glucose and β-Ketone Monitoring System
General Device Characteristic Similarities		
Intended Use	Quantitatively measure blood glucose or blood ketone in fresh capillary whole blood drawn from fingertips. The system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control and should only be used by a single patient and it should not be shared. It is not intended for diagnosis or screening of diabetes or for neonatal use.	Same
Glucose measuring range	20-600 mg/dL	Same
Ketone measuring range	0.1 – 8.0 mmol/L	Same
Glucose Test Strips Active reagent:	glucose oxidase	Same
Ketone Test Strips Active reagent	β-hydroxybutyrate dehydrogenase	Same

General Device Characteristic Differences		
Battery	2 × CR2032, 3 volt coin cell battery	3 volt coin cell battery CL2450
Operation Condition	10°C - 40°C (50-104°F), 20~90% RH	14°C - 40°C 10~90% RH
Hematocrit Range	20%-60%	25%-60%
Sample size	0.5 µL glucose 0.8 µL ketone	0.3 µL glucose 0.8 µL ketone

VI Standards/Guidance Documents Referenced:

IEC 61010-1 Edition 3.1 2017-01 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition

IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Glucose:
A within-run precision study using 3 lots of MultiSure GK Blood Glucose test strip was performed. Venous blood was spiked to 5 concentrations (30-50, 51-110, 111-150, 151-250, 250-400 mg/dL). For each sample concentration, 10 meters were used, with 10 measurements taken by each meter (i.e., 100 measurements per concentration per lot). Results are summarized below:

Glucose Within Run Precision

Venous Blood Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV
Level 1 (30-50)	Lot 1	100	45	1.8	4.1%
	Lot 2	100	45	2.0	4.5%
	Lot 3	100	45	2.0	4.5%
	Combined	300	45	2.0	4.4%

Venous Blood Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV
Level 2 (51-110)	Lot 1	100	89	2.3	2.6%
	Lot 2	100	90	2.4	2.6%
	Lot 3	100	89	2.4	2.6%
	Combined	300	89	2.3	2.6%
Level 3 (111-150)	Lot 1	100	119	3.4	2.8%
	Lot 2	100	119	3.0	2.6%
	Lot 3	100	119	3.3	2.8%
	Combined	300	119	3.2	2.7%
Level 4 (151-250)	Lot 1	100	220	4.8	2.2%
	Lot 2	100	221	4.8	2.2%
	Lot 3	100	220	4.7	2.1%
	Combined	300	220	4.8	2.2%
Level 5 (251-400)	Lot 1	100	330	7.7	2.3%
	Lot 2	100	330	7.5	2.3%
	Lot 3	100	329	8.0	2.4%
	Combined	300	329	7.7	2.3%

Intermediate precision of the MultiSure GK Link Blood Glucose and Ketone Monitoring System was evaluated using 5 levels of glucose control solutions (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL) using 3 lots of MultiSure GK Blood Glucose test strip was performed on five levels of control solutions. The tests were conducted with 10 meters, one measurement per meter per day at the five different glucose ranges, for ten days for a total of 300 glucose results per each glucose level. Results are summarized below:

Glucose Control Levels (mg/dL)	Strip lot	N	Mean (mg/dL)	SD (mg/dL)	CV
L1 (30-50)	Lot 1	100	41	0.7	1.7%
	Lot 2	100	40	1.0	2.6%
	Lot 3	100	40	1.3	3.4%
	Combined	300	40	1.1	2.8%
L2 (51-110)	Lot 1	100	70	0.5	0.7%
	Lot 2	100	70	0.7	1.0%
	Lot 3	100	68	0.7	1.1%
	Combined	300	69	1.3	1.8%
L3 (111-150)	Lot 1	100	121	0.6	0.5%
	Lot 2	100	121	0.9	0.7%
	Lot 3	100	121	1.2	1.0%
	Combined	300	121	0.9	0.7%

Glucose Control Levels (mg/dL)	Strip lot	N	Mean (mg/dL)	SD (mg/dL)	CV
L4 (151-250)	Lot 1	100	221	1.4	0.7%
	Lot 2	100	221	1.5	0.7%
	Lot 3	100	223	1.7	0.8%
	Combined	300	222	1.7	0.8%
L5 (251-400)	Lot 1	100	328	2.2	0.7%
	Lot 2	100	329	2.6	0.8%
	Lot 3	100	331	1.7	0.5%
	Combined	300	329	2.4	0.7%

Ketone:

The sponsor performed a ketone repeatability (within-run) precision study using 3 lots of MultiSure GK Blood Ketone test strip. Venous blood samples that were spiked to 5 ketone concentrations (0.4-0.6, 1.5-2.5, 3.0-4.5, 5.0-6.5, 6.5-8.0 mmol/L) were used. For each sample concentration, 10 meters were used, with 10 measurements taken by each meter (i.e., 100 measurements per concentration per lot). Results are summarized below:

Ketone Within Run Precision

Venous Blood Ketone Level (mmol/L)	Lot	N	Mean (mmol/L)	SD (mmol/L)	CV (%)
Level 1 (0.4-0.6)	Lot 1	100	0.5	0.06	11.6%
	Lot 2	100	0.5	0.06	10.5%
	Lot 3	100	0.5	0.05	10.2%
	Combined	300	0.5	0.06	10.8%
Level 2 (1.5-2.5)	Lot 1	100	2.2	0.07	3.1%
	Lot 2	100	2.2	0.07	3.3%
	Lot 3	100	2.2	0.07	3.4%
	Combined	300	2.2	0.07	3.2%
Level 3 (3.0-4.5)	Lot 1	100	4.0	0.14	3.5%
	Lot 2	100	4.0	0.13	3.4%
	Lot 3	100	4.0	0.14	3.6%
	Combined	300	4.0	0.14	3.5%
Level 4 (5.0-6.5)	Lot 1	100	6.0	0.18	3.1%
	Lot 2	100	6.0	0.19	3.1%
	Lot 3	100	6.0	0.20	3.4%
	Combined	300	6.0	0.19	3.2%
Level 5 (6.5-8.0)	Lot 1	100	7.1	0.20	2.8%
	Lot 2	100	7.1	0.18	2.5%
	Lot 3	100	7.1	0.18	2.6%
	Combined	300	7.1	0.19	2.6%

Intermediate precision was performed using two levels of β-ketone control solutions (0.1-0.7 and 1.4-2.0 mmol/L). Testing was conducted over 10 days with three test strip lots and 10 meters. For each control solution 10 replicates were taken each day resulting in 100 individual measurements per level:

Ketone Control Level (mmol/L)	Strip lot	N	Mean (mmol/L)	SD (mmol/L)	CV (%)
L1 (0.1-0.7)	Lot 1	100	0.4	0.02	4.7%
	Lot 2	100	0.4	0.02	4.2%
	Lot 3	100	0.4	0.02	5.6%
	Combined	300	0.4	0.02	5.1%
L2 (1.4-2.0)	Lot 1	100	1.7	0.01	0.3%
	Lot 2	100	1.7	0.02	1.4%
	Lot 3	100	1.7	0.02	0.9%
	Combined	300	1.7	0.05	3.1%

2. Linearity:

Glucose linearity from 20 to 600 mg/dL was previously established in k141036.

The ketone linearity of MultiSure GK Link Blood Ketone Monitoring System was evaluated using venous whole blood spiked with β-hydroxybutyrate. Seven whole blood samples were adjusted to the following β-hydroxybutyrate concentrations: 0.06, 0.55, 2.11, 4.49, 6.12, 7.35, and 8.40 mmol/L. The concentrations were assigned using the Beckman Coulter AU480 analyzer with STANBIO β-Hydroxybutyrate LiquiColor Test Kit.

The summary of the linear regression analysis for each lot was as follow:

Lot #	Slop	y-intercept	R^2 value
Lot 1	0.9833	0.0542	0.9992
Lot 2	0.9909	0.0357	0.9992
Lot 3	0.9928	0.0298	0.9993

The results of the study support the sponsor's claimed (β-ketone) measuring range of 0.1-0.8 mmol/L.

Validation testing was performed demonstrating that the meter displays a flashing Ket icon and 'HI" when the ketone measurement result is greater than 8.0 mmol/L and a flashing Ket icon with "LO" when the ketone measurement result is less than 0.1 mmol/L as intended.

3. Analytical Specificity/Interference:

Glucose interference was previously established in k141036.

To evaluate the effect of potential interfering exogenous and endogenous substances on the ketone measurement function, three venous whole blood samples with ketone concentrations of 0-0.8 mmol/L, 2.0-3.5 mmol/L and 5.0-7.0 mmol/L were used. Each sample was divided into a control sample (with no added interferent) and a test sample (with added potential interferent). The results from the test samples obtained using the candidate system were compared to the results obtained with the control samples using the candidate system. The sponsor defined no significant interference as bias within 0.3 mmol/L for β-ketone < 1.5 mmol/L and ≤ 20% for β-ketone ≥1.5 mmol/L. The following table lists the highest tested concentration of each substance at which no significant interference was detected.

Substance	Highest concentration at which no significant interference is observed (mg/dL)
Acetaminophen	20
Acetone	10
Acetoacetate	10
Ascorbic acid	4
Bilirubin	10
Captopril	10
Cholesterol	500
Creatinine	6
Dopamine	2
Glucose	900
Ibuprofen	50
L-DOPA	3
Methyl-Dopa	7.5
N-acetylcysteine	10
Tetracycline	10
Tolazamide	15
Triglyceride	750
Uric acid	20
Salicylate	60
Tolbutamide	100

The sponsor includes the following glucose limitations in the labeling for the MultiSure GK Link Blood Glucose and Ketone Monitoring System:

- If you are taking acetaminophen or acetaminophen containing drugs (for example Tylenol; at blood concentrations > 10 mg/dL) you may get inaccurate results with this system.
- If you are taking Tolbutamide at blood concentrations > 15 mg/dL, you may get inaccurate results with this system.
- If you are taking Ibuprofen or Ibuprofen containing drugs as Advil at blood concentrations > 40 mg/dL, you may get inaccurate results with this system.
- If you are taking Paralidoxime Iodide (PAM) or Paralidoxime Iodide (PAM) containing drugs at blood concentrations > 50 mg/dL, you may get inaccurate results with this system.

- If you have a disease or condition in which uric acid levels in your blood may be elevated (>15 mg/dL), such as gout, you may get inaccurate results with this system.
- 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.

4. Assay Reportable Range:

   20 - 600 mg/dL for glucose
   0.1 - 8.0 mmol/L for ketone

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

   Traceability
   The system reports plasma-equivalent glucose values and is calibrated by using the YSI 2300 STAT PLUS Glucose Analyzer, which is traceable the NIST SRM 917b glucose reference material.

   The system reports plasma-equivalent ketone values and is calibrated by using STANBIO ß-Hydroxybutyrate LiquiColor Test Kit and STANBIO β-Hydroxybutyrate Linearity Standard on the Beckman Coulter AU480 analyzer.

   Test Strip Stability
   Both the MultiSure GK Blood Glucose Test Strips and the MultiSure GK Ketone Glucose Test Strips are provided packaged in vials and as individually wrapped single strips.

   Shelf-life and open vial stability for the MultiSure GK Blood Glucose Test Strips were previously evaluated in k141036 to support the claimed shelf life of 24 months when stored under conditions of 39-86°F and a relative humidity of 10-85% and a 6 month open vial claim when stored under these same conditions.

   Shelf-life for the individually wrapped MultiSure GK Blood Glucose Test Strips was assessed with real-time testing. The study protocols and acceptance criteria were reviewed and found acceptable to support the sponsor's claimed shelf-life stability of 24 months when stored at recommended storage conditions of 39-86°F (10-30°C) and 10-85% relative humidity.

   Shelf-life and open vial stability for the MultiSure GK Ketone Test Strips were evaluated using real-time testing. Study protocols and acceptance criteria were reviewed and found acceptable to support the sponsor's claimed shelf life of 18 months when stored at the recommended storage conditions of 39-86°F (10-30°C) and 10-85% relative humidity and an open vial stability of 3 months when stored under these same conditions.

   Shelf-life for the individually wrapped MultiSure GK Ketone Test Strips was previously evaluated in k182593 to support the claimed shelf life of 18 months when stored under conditions of 39-86°F and a relative humidity of 10-85%.

6. Detection Limit:

   See 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 the lay-use studies below, section VII.C.3, for glucose and ketone accuracy performance in the hands of the intended user.

   Ketone Method Comparison:
   To assess ketone measurement system accuracy performance, results from the MultiSure GK Link Blood Glucose and Ketone Monitoring System obtained in the hands of trained professionals were compared to the comparator method, STANBIO ß-Hydroxybutyrate LiquiColor Test Kit tested with Beckman Coulter AU480 Analyzer. A total of one hundred (100) capillary whole blood samples, ranging in ketone concentrations of 0.04 -7.99 mmol/L, were tested using three ketone test strip lots. To obtain blood samples with β-ketone values at the higher end of the claimed ketone measurement range, capillary blood samples were spiked with β-ketone. The results relative to the comparator method are summarized below:

System Accuracy Results for Ketone concentration <1.5 mmol/L		
Within ± 0.15 mmol/L	Within ± 0.225 mmol/L	Within ± 0.30 mmol/L
32/34 (94.1%)	34/34 (100%)	34/34 (100%)

System Accuracy Results for Ketone concentration ≥1.5 mmol/L		
Within ± 10%	Within ± 15%	Within ± 20%
64/66 (97.0%)	66/66 (100%)	66/66 (100%)

Linear regression analysis: $y = 0.9886x + 0.049$, $R^2 = 0.9967$

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):

To assess the glucose accuracy performance of the combined MultiSure GK Link Blood Glucose and Ketone Monitoring System in the hands of the intended user the sponsor performed studies where lay users obtained their own glucose and ketone results.

Glucose:
A total of 350 lay-user participants obtained their own fingerstick samples and glucose results using only the system components and instructions provided in the labeling. Three glucose test strip lots were used for the study. The glucose concentrations of the participant samples ranged from 65 to 500 mg/dL as measured by the comparator method (YSI 2300 analyzer). Glucose results obtained by the participants using the candidate device were compared to results obtained using the comparator method and are summarized in the tables below:

For glucose concentration <75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	within ± 20 mg/dL
9/12 (75%)	12/12 (100%)	12/12 (100%)	12/12 (100%)

For glucose concentration ≧75 mg/dL			
within ± 5 %	within ± 10%	within ± 15%	within ± 20%
147/338 (44.6%)	307/338 (91.1%)	338/338 (100%)	338/338 (100%)

For combined glucose concentrations			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
153 / 350 (43.7%)	317 / 350 (90.6%)	350 / 350 (100%)	350 / 350 (100%)

Linear regression analysis: $y = 0.9955x + 1.8314$, $R^2 = 0.9716$

Extreme Glucose Study**:**

An additional study was conducted to evaluate the glucose accuracy performance of MultiSure GK Link Blood Glucose and Ketone Monitoring System in the extreme lower and upper ends of the claimed measuring range using 100 altered capillary fingerstick samples and 3 test strip lots. Fifty (50) samples were glycolyzed to achieve samples with glucose concentrations less than 80 mg/dL (21-79 mg/dL) and 50 samples are spiked to achieve concentrations greater than 250 mg/dL (260 -593 mg/dL). Results from the candidate device were compared to results obtained using the comparator method (YSI 2300 analyzer) and are summarized in the tables below:

For glucose concentration <80 mg/dL			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
18/50 (36%)	40/50 (80%)	50/50 (100%)	50/50 (100%)
For glucose concentration >250 mg/dL			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
34/50 (68%)	42/50 (84%)	50/50 (100%)	50/50 (100%)

Ketone:

A total of 100 lay user participants obtained their own fingerstick samples and ketone results using only the system components and instructions provided in the labeling. The ketone concentrations in the participant samples ranged from 0.05-2.65 mmol/L as measured by the comparator method (STANBIO ß-Hydroxybutyrate LiquiColor Test Kit tested with Beckman Coulter AU480 Analyzer). Ketone results obtained by the participants using the candidate device were compared to results obtained using the comparator method and are summarized in the tables below:

System Accuracy Results for Ketone Concentration <1.5 mmol/L		
Within ± 0.15 mmol/L	Within ± 0.225 mmol/L	Within ± 0.30 mmol/L
76/90 (84.4%)	87/90 (96.7%)	90/90 (100%)

System Accuracy Results for Ketone concentration ≧1.5 mmol/L		
Within ± 10%	Within ± 15%	Within ± 20%
8/10 (80%)	9/10 (90%)	10/10 (100%)

Linear regression analysis: $y = 0.977x + 0.0347$; $R^2 = 0.998$

Usability Assessment:

The usability of the system was assessed by questionnaires given to the operators of the system following the conclusion of the glucose and ketone lay user studies where the participants read the labeling documents without any assistance or guidance. The study participants then independently completed meter setup, performed glucose/ketone measurement using blood/control and retrieved/marked the test results in the same way as

home users. The study participants were asked to complete a usability questionnaire regarding ease of understanding of information in the user manual and the ease of use when performing a blood ketone test. The study demonstrated that users of the device were able to understand and follow the instructions provided in the labeling to perform tasks involved in blood glucose/ketone testing.

Readability:
The MultiSure GK Link Blood Glucose and Ketone Monitoring System user manual and the MultiSure GK blood glucose and ketone test strips were assessed for readability using the Flesch-Kincaid assessment demonstrating that the labeling was written at an 8th grade reading level or less.

D Clinical Cut-Off:

Not Applicable.

E Expected Values/Reference Range:

The sponsors included the following in the labeling:

Glucose
The ideal ranges for adults without diabetes are:

- Under 100 mg/dL before meals.
- Under 140 mg/dL after meals.

American Diabetes Association, Standard of Medical Care in Diabetes 2020, Vol. 43 (Suppl. 1).

Ketone

Based on published literature, the sponsor included < 0.6 mmol/L as the expected value for ketones and cites the following reference:

Tietz NW. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Company; 4th Edition.

F Other Supportive Instrument Performance Characteristics Data:

Hematocrit:
Previously established in k141036 and k182593 to support the claimed hematocrit range of 20-60% for glucose and ketone testing, respectively

Altitude:
Previously established in k141036 and k182593 to support the use of the device up to 10,335 ft. (3150 meters) for glucose and ketone testing, respectively.

Operating Conditions:
The sponsor performed operating condition studies to evaluate the operating temperature

and relative humidity (RH) ranges of the new combination system. The results support the claimed operating condition range of 10˚C~40˚C (50 °F to 104°F) and 20~90% relative humidity for both glucose and ketone functionalities.

Sample Volume:
Established in k141036 and k182593 to support a 0.5 µL sample volume for glucose and 0.8 µL sample volume for ketone.

Infection Control:
The device system is intended for single patient use only. Disinfection efficacy studies were performed previously in k131750 on the materials comprising the meter by an outside commercial testing lab demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Healthcare Bleach Germicidal Wipes (EPA Registration # 67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in ketone or glucose performance or external materials of the meter after 260 cleanings and disinfection steps with the Clorox Healthcare Bleach Germicidal wipes. The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

Flex Studies:
Studies were performed to assess the effect of the following on both the glucose and ketone measurement functions of the candidate system: used test strip insertion, test strip removal during measurement countdown, intermittent sampling, sample perturbation, and dropping. The testing demonstrated that the MultiSure GK Link Blood Glucose and Ketone Monitoring System is robust to these use scenarios and that either an error message is returned, or an accurate result is displayed.

EMC:
EMC testing was certified and compliance certificates provided documenting that acceptable electromagnetic testing (EMC) had been performed.

Glucose Test Strip Lot Release Protocol:
Glucose test strip lot release protocols and criteria were reviewed and found to be acceptable.

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.