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

A. 510(k) Number:

k161299

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood samples drawn from the fingertips, forearm, or palm and venous (for Pro system only)

D. Type of Test:

Quantitative, amperometric method, Glucose Dehydrogenase (FAD-GDH)

E. Applicant:

Apex Biotechnology Corp.

F. Proprietary and Established Names:

BGM014 Blood Glucose Monitoring System
BGM014 Pro Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345, Glucose test system
   21 CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:

   Class II
   Class I, reserved

3. Product code:

   NBW- System, Test, Blood Glucose, Over The Counter
   LFR- Glucose Dehydrogenase, Glucose
   JJX- Single (Specified) Analyte Controls (Assayed and Unassayed)

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. Indication(s) for use:

   BGM014 System:
   The BGM014 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alterative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is intended for self-testing by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis of or screening for diabetes or for neonatal use.

   The BGM014 Blood Glucose Monitoring System is comprised of the BGM014 Blood Glucose Meter and BGM014 Blood Glucose Test Strip.

   The Contrex Plus 5 glucose control solution is used with the BGM014 Meter and BGM014 Test Strip to verify that the meter and test strip are working together properly and that the test is performing correctly.

   BGM014 Pro System:
   The BGM014 Pro Blood Glucose Monitoring System is intended for the quantitatively measurement of glucose in venous whole blood, or capillary whole blood drawn from fingertips, palm, or forearm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is intended for multiple-patient use in professional healthcare settings as an aid to monitor effectiveness of diabetes control program. This system should only be used with single use, auto-disabling lancing devices. It is not indicated for the diagnosis of or screening for diabetes or for neonatal use.

   The BGMO14 Pro Blood Glucose Monitoring System is comprised of the BGMO 14 Pro Blood Glucose Meter andBGMO14 Pro Blood Glucose Test Strip

   The Contrex Plus 5 glucose control solution is used with the BGMO 14 Pro Meter and BGMO14 Pro Test Strip, to verify that the meter and test strip are working together properly and that the test is performing correctly.

3. Special conditions for use statement(s):

For the BGM014 Blood Glucose Monitoring System:

- For single-patient use only
- Should not be used to test critically ill patients.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic - hyperosmolar state, with or without ketosis.
- Not for use on neonates.
- Altitude higher than 10,335 feet may cause inaccurate results.
- Hematocrit range higher than 70% or lower than 10% can cause inaccurate results.
- Severe dehydration may lead to inaccurate blood glucose test result.
- For In vitro diagnostic only.
- For over the counter use.
- Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly).
- Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs).
- Alternative site measurements should never be used for insulin dosing calculations.

For the BGM014 Blood Glucose Monitoring System:

- This system should only be used with single use, auto-disabling lancing devices
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- This device has not been evaluated for use in critically ill people.
- Do not test on arterial blood samples.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic - hyperosmolar state, with or without ketosis.
- Not for use on neonates.
- Altitude higher than 10,335 feet may cause inaccurate results.
- Hematocrit range higher than 70% or lower than 10% can cause inaccurate results.
- Severe dehydration may lead to inaccurate blood glucose test result.
- For In vitro diagnostic only.
- For over the counter use.
- Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly).
- Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs).
- Alternative site measurements should never be used for insulin dosing calculations.

4. Special instrument requirements:

BGM014 Blood Glucose Meter
BGM014 Pro Blood Glucose Meter

I. Device Description:

The BGM014 Blood Glucose Monitoring System is comprised of the BGM014 meter, BGM014 test strips, and Contrex Plus 5 control solutions (Level 1, Level 2, and Level 3) along with labeling and packaging. Controls are not included in the kit but are sold separately. The system is for self-testing (home use).

The BGM014 Pro Blood Glucose Monitoring System is comprised of the BGM014 Pro meter, BGM014 Pro test strips, and Contrex Plus 5 control solutions (Level 1, Level 2, and Level 3) along with labeling and packaging. The system is for multiple-patient use in professional healthcare settings.

The meters include a variety of features, such as the ability to store blood test results with a date and time stamp and also a port to allow data upload to compatible data management software.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   AutoSure HT Blood Glucose Monitoring System
   Contrex Plus 4 Glucose Control Solutions

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

   k131750

3. Comparison with predicate:

Similarities and Differences			
Characteristic	**Candidate Device** BGM014 Blood Glucose Monitoring System	**Candidate Device** BGM014 Pro Blood Glucose Monitoring System	**Predicate Device** AutoSure HT Blood Glucose Monitoring System (k131750)
Intended use	Intended to be used for the quantitative measurement of glucose as an aid in monitoring the effectiveness of a diabetes control program.	Same	Same
Methodology	Glucose Dehydrogenase	Glucose Dehydrogenase	Glucose Oxidase

Intended use population	Single-Patient use	Multi-Patient Use	Single-Patient Use
Sample type	Capillary whole blood samples drawn from the fingertips, forearm, or palm	Capillary whole blood samples drawn from the fingertips, forearm, or palm and venous whole blood	Capillary whole blood samples drawn from the fingertips, forearm, or palm
Glucose test range	20-600 mg/dL	Same	Same
Hematocrit	10-70%	Same	Same
Maximum altitude	10,335 feet	Same	Same
Intended use population	Single-Patient use	Multiple-Patient Use	Single-Patient Use
Data upload	Yes	Yes	No
Minimum Sample size	0.8µl	0.8µl	0.9µl
Test time	8 seconds	8 seconds	6 seconds

Similarities and Differences for Control Solutions			
Characteristic	**Candidate Device** Contrex Plus 5 control solutions	**Candidate Device** Contrex Plus 5 control solutions	**Predicate Device** Contrex Plus 4 control solutions (k131750)
Intended Use	To verify that the meter and test strip are working together properly and that the test is performing	To verify that the meter and test strip are working together properly and that the test is	Same
Control solutions	Level 1, Level 2, and Level 3	Level 1, Level 2, and Level 3	Same

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

CLSI EP05-A3, evaluation of precision of quantitative measurement procedures; approved guideline- third edition. (In Vitro Diagnostics)

CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003)

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

IEC/EN 61010-1, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements None, Ed 3.0 (2010)

L. Test Principle:

The BGM014/Pro Blood Glucose Monitoring Systems are electrochemical biosensors using a glucose-dehydrogenase, (*Aspergillus sp.*), along with a redox mediator on a disposable test strip (the electrochemical embedded sensor), and a handheld device to measure current generated by test strip. The software in the hand held device converts the measured current into glucose concentration, where generated current is directly proportional to glucose concentration.

M. Performance Characteristics (if/when applicable):

BGM014 and BGM014 Pro Blood Glucose Monitoring Systems only differ in name and intended use (single-patient use vs. multiple-patient use); therefore, performance data provided in this section is applicable for both systems.

1. Analytical performance:

   a. *Precision/Reproducibility:*
   The sponsor performed within-run precision studies using venous blood from one donor adjusted to 5 glucose levels (30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151- 250 mg/dL and 251-400 mg/dL) tested on ten BSM014 meters with three lots of strips. Within-run test was performed every day for 20 days. Each sample was tested in 10 replicates per meter and per strip lot, giving a total of 200 measurements per lot for a total of 600 measurements for each glucose level. Results are summarized below:
   Within-run precision:

Glucose Level (mg/dL)	Number of readings	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	600	40	3.0	7.5
51-110	600	70	3.0	4.3
111-150	600	122	3.8	3.1
151-250	600	221	6.6	3.0
251-400	600	331	6.7	2.0

Intermediate precision was evaluated using three levels of glucose control solutions, Level 1, 2 and 3. Each glucose level was analyzed once per day on 10 meters using 3 lots of test strips over 20 days. Results for intermediate, between-day precision are summarized below.

Intermediate precision- Between Run:

Glucose Level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	40	1.3	3.1
Level 2	121	1.6	1.3
Level 3	331	2.3	0.7

b. *Linearity/assay reportable range:*

Linearity testing was performed using venous whole blood samples. The evaluation was conducted using eight different glucose concentrations according to the reference (19.8 mg/dL, 50 mg/dL, 80 mg/dL, 110 mg/dL, 201 mg/dL, 306 mg/dL, 527 mg/dL, 613 mg/dL), YSI. Each sample was measured in replicates of 40 with 3 test strip lots and ten BGM014 meters and the values compared to a laboratory reference method (YSI 2300 analyzer). Results from the regression analysis:

Strip Lot	Slope	Y-Intercept	R^2
1	0.9927	0.0132	0.9993
2	1.0062	-1.2672	0.9996
3	1.0051	-1.8185	0.9996

The results of the study support the sponsor's claimed glucose measurement range of 20 to 600 mg/dL. If a sample is less than 10 mg/dL, the result is flagged by the meter as LO. If a sample result exceeds 600 mg/dL, the result is flagged by the meter as HI.

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

Traceability
The BGM014/Pro Blood Glucose Monitoring Systems are traceable to NIST SRM 917c glucose.

Test strips stability:
Test strip stability was assessed for test strip vials and individually wrapped test strips in real-time studies. Testing protocols and acceptance criteria were reviewed and found to be acceptable. The manufacture claims a shelf life stability of 24 months and open vial stability (for the vials of test strips) of 6 months at the recommended storage conditions of 4℃-30℃ (39.2°F -86°F) and 10-85% relative humidity.

Control Solution Stability and Value Assignment:
The stability and value assignment of the Contrex Plus 5 Control solutions were assess in real-time studies. Stability testing protocols and acceptance criteria for the glucose control solutions were reviewed and found to be acceptable. The manufacturer claims a shelf life stability of 24 months and an open-vial stability of 3 months at the recommended storage temperatures of 39.2°F - 86°F (4°C to 30°C).

Value Assignment:
Value assignment on glucose control solutions is performed using 3 lots of Contrex Plus 5 control solutions (for all 3 levels) using two BGM014 Blood Glucose Monitoring systems daily for 10 days, with two tests/meter for each control solution, for a total of 360 test results. Results were verified against values from the YSI-2300 reference method and using pre-determined acceptance criteria for glucose recovery within a specified range for each control lot/level. The acceptable control range is established using the mean value of each control solution level. Glucose control ranges are lot dependent and are listed on the test strip vial label for each lot and level.

d. Detection limit:

The reportable range for the BGM014/Pro Blood Glucose Monitoring Systems is 20-600 mg/dL. This range was verified by the linearity study (M.1.b).

e. Analytical specificity:

Interference studies were performed by adding endogenous and exogenous substances, each at two or more levels (normal/therapeutic and high) to venous whole blood samples containing two different glucose levels (70-90 and 300-330 mg/dL). Each sample was measured in replicates of ten on the BGM014 glucose meter and the % difference between the results obtained with the test samples was compared to those obtained using the corresponding control sample (containing no added interferent). The table below shows the highest levels tested at which no significant interference compared to YSI 2300 analyzer (defined by the sponsor as ≤ +/- 10%) was observed:

Substance	**Concentration with no Significant Interference (mg/dL)**
Acetaminophen	7.5 mg/dL
Ascorbic Acid	6.0 mg/dL
Bilirubin	20.5 mg/dL
Cholesterol	700 mg/dL
Creatinine	5.9 mg/dL
Dopamine	0.1 mg/dL
Fructose	29 mg/dL
Galactose	17.4 mg/dL
Gentisic Acid	2 mg/dL

Substance	Concentration with no Significant Interference (mg/dL)
Glutathione	84 mg/dL
Hemoglobin	215 mg/dL
Ibuprofen	50 mg/dL
Icodextrin	1094 mg/dL
Lactose	25 mg/dL
L-DOPA	3.0 mg/dL
Maltose	200 mg/dL
Maltotetraose	120 mg/dL
Maltotriose	240 mg/dL
Mannitol	30 mg/dL
Mannose	4.0 mg/dL
Methyl-Dopa	0.75 mg/dL
Paralidoxime Iodide (PAM)	125 mg/dL
Salicylic Acid	30 mg/dL
Sorbitol	0.2 mg/dL
Tetracycline	1.5 mg/dL
Tobutamide	64 mg/dL
Tolazamide	23 mg/dL
Triglyceride	3190 mg/dL
Uric Acid	10.25 mg/dL
Xylitol	0.1 mg/dL
Xylose	7.5 mg/dL

The sponsor has included the following in the labeling:

- If you have certain conditions that may cause your blood level of uric acid to rise (>10.25 mg/dL in your blood), such as gout or kidney disease, then your blood glucose results may be inaccurate with this meter. If you are unsure, then ask your doctor.
- Do not test blood glucose during or soon after a Xylose Absorption test (>7.5 mg/dL in your blood) since your blood glucose results may be inaccurate with this meter.
- If you are taking high doses of the pain medication acetaminophen (such as Tylenol, certain cold or flu remedies, and certain prescription drugs) (>7.5 mg/dL in your blood), then you should know that this drug might affect the reliability of your blood glucose results. If you are unsure, please ask your healthcare professional.
- If you are taking high doses of the Tolazamide (>23 mg/dL in your blood), then you should know that this drug might affect the reliability of your blood glucose results. If you are unsure, please ask your healthcare professional.
- If you are taking high doses of the Paralidoxime Iodide (PAM) (>125 mg/dL in

your blood), then you should know that this drug might affect the reliability of your blood glucose results. If you are unsure, then ask your doctor.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

To assess system accuracy for capillary samples, results from the BGM014 Blood Glucose Monitoring system were compared to a reference method, YSI2300. Capillary fingertip, forearm and palm samples were collected from 152 participants with glucose concentrations ranging from 37 – 457 mg/dL for the fingerstick and 62-417 mg/dL for forearm and palm. To obtain extreme blood glucose concentrations some samples were altered. The results of the BGM014 BGM system relative to YSI are summarized below:

Summary of Fingertip, Palm and Forearm Samples vs. YSI

For glucose concentrations <75mg/dL			
Sample Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Fingertip	18/22 (82%)	22/22 (100%)	22/22 (100%)
Palm	9/11 (82%)	11/11 (100%)	11/11 (100%)
Forearm	9/11 (82%)	11/11 (100%)	11/11 (100%)

For glucose concentrations ≥75mg/dL				
Sample Site	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Fingertip	76/130 (58%)	117/130 (90%)	130/130(100%)	130/130 (100%)
Palm	68/126 (54%)	114/126 (90%)	126/126(100%)	126/126 (100%)
Forearm	85/126 (67%)	114/126 (90%)	125/126 (99%)	126/126 (100%)

Linear regression analysis

Sample Site	**Slope**	**Intercept**	**R^2**	**N**	**Glucose range (mg/dL)**
Fingertip	0.9886	-2.301	0.9932	152	37-457
Palm	0.9798	-1.0743	0.9903	137	62-417
Forearm	0.9806	2.689	0.989	137	62-417

Venous accuracy study:
To assess system accuracy for venous samples, results from the BGM014 Blood Glucose Monitoring system were compared to a reference method, YSI2300. Venous samples were collected using lithium heparin tubes from 137 participants with glucose

concentrations ranging from 62-417 mg/dL. To obtain extreme blood glucose concentrations some samples were altered. The results of the BGM014 BGM system relative to YSI are summarized in the tables below:

Summary of Venous Samples vs YSI

For glucose concentrations <75mg/dL		
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
10/11 (91%)	11/11 (100%)	11/11 (100%)

For glucose concentrations ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15 %	Within ± 20%
87/126 (64%)	114/126 (90%)	125/126 (99%)	126/126 (100%)

Linear regression analysis

Sample Site	**Slope**	**Intercept**	**R^2**	**N**	**Glucose range (mg/dL)**
Venous	0.994	-2.511	0.9925	137	62-417

The labeling states that venous blood samples should be collected using lithium heparin tubes.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable.

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

User Performance Studies:
To assess the performance of the BGM014 System in the hands of the intended users the sponsor performed a study with 137 lay user participants, who collected their own fingerstick, palm and forearm samples. Samples ranged from 62-417 mg/dL as measured by YSI. Results were analyzed by comparing blood glucose results from the BGM014 meter obtained by the lay user against the YSI 2300 reference value obtained by healthcare professionals. The results are summarized in the tables below:

Fingerstick vs YSI:

For Glucose Concentration < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
10/11 (91%)	11/11 (100%)	11/11 (100%)	
For glucose concentrations ≥75mg/dL			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
72/126 (57%)	115/126 (91%)	125/126 (99%)	126/126 (100%)

Palm Test vs YSI:

For Glucose Concentration < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
8/11 (73%)	10/11 (91%)	11/11 (100%)	
For glucose concentrations ≥75mg/dL			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20%
78/126 (62%)	114/126 (90%)	125/126 (99%)	126/126 (100%)

Forearm Test vs YSI:

For Glucose Concentration < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
9/11 (82%)	10/11 (91%)	11/11 (100%)	
For glucose concentrations ≥75mg/dL			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20%
72/126 (57%)	115/126 (91%)	125/126 (99%)	126/126 (100%)

Linear Regression Analysis:

Sample Site	Slope	Intercept	R2	N	Glucose Concentration (mg/dL)
Fingertip	0.9816	-1.3045	0.9900	137	62-417
Palm	0.9895	-2.741	0.9898	137	62-417
Forearm	0.981	2.3798	0.9877	137	62-417

During the lay user study participants were asked to complete a questionnaire to evaluate the use of the device and the clarity of user manual. Overall the users indicated that they could successfully conduct the test.

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   Expected glucose values for people without diabetes:
   Before a meal (fasting): 70-100 mg/dL
   2 h after a meal: < 140mg/dL

   Reference:
   American Diabetes Association, Standards of Medical Care in Diabetes—2016. Diabetes Care, Vol.39, Supplement 1.

N. Instrument Name:

BGM014 Blood Glucose meter
BGM014 Pro Blood Glucose meter

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?

   Yes __ _____ or No ____x____

2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
   Yes ____x____ or No _____

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

4. Specimen Sampling and Handling:
   This device is intended to be used with capillary whole blood from the fingertip, palm and forearm which can be applied directly to the test strip.

5. Calibration:
   This system has an auto-coding feature; coding of the meter by the user is not necessary.

6. Quality Control:
   Three levels of controls are available for use with this meter. The control solutions must be purchased separately using the contact information provided in the user guide.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. **Sample volume study**:
   The sponsor performed a study to verify the test strip minimum sample volume requirement (0.8 µL) and the test strip fill error ("Er" 3) function established for the BGM014 Blood Glucose Meter. Blood samples were tested at 6 sample volumes: 0.6, 0.7, 0.8, 0.9, and 1µl and values obtained were compared to the reference, YSI values. Results support the claimed minimum sample volume of 0.8 µL and the error code for insufficient sample volume.

2. **Altitude Study:**
   To assess the effect of altitude, venous whole blood samples were adjusted to 5 glucose concentrations: 50, 120, 220, 330 and 450 mg/dL and tested at sea level and 10,335 feet above sea level using 10 meters and 3 test strip lots. Results were compared to YSI reference values. The results demonstrate acceptable bias to YSI to support the claims in the labeling that altitudes up to 10,335 feet have no significant effect on blood glucose measurements from the BGM014 system.

3. **Hematocrit Study:**
   The effect of different hematocrit levels on the performance of the BGM014 glucose meter was evaluated using venous whole blood samples with hematocrit levels of 10, 20, 30, 35, 43, 50, 55, 60 and 70%, at glucose concentrations of 40, 60, 130, 300 and 500 mg/dL using 10 meters and 3 test strip lots. For each blood sample, individual glucose readings taken on the BGM014 glucose meter were compared to YSI reference values to calculate the bias. The results demonstrate acceptable bias for hematocrit levels between

10-70%.

4. **Readability Assessment**
   The readability of the labeling (user manual, quick reference guide and test strip insert) using Flesch-Kincaid's analysis were found to be written not higher than 8th grade level.

5. **Test System Operating Conditions:**
   The effect of temperature (41 - 113°F (5 - 45°C) and relative humidity (RH) (20– 90%) on the BGM014 glucose meter was evaluated using venous blood samples at 60, 120, 200 and 400 mg/dL glucose. Twenty replicates were tested at each of the multiple temperature and humidity combinations that included the extreme combinations (low temperature/low humidity, low temperature/high humidity, high temperature/low humidity, and high temperature/high humidity). Meter results were compared to YSI values. The study results support the operating conditions claims in the labeling that the system can be used in conditions of 41 - 113°F (5 - 45°C) with relative humidity of 20–90% RH.

6. **EMC Testing:**
   The sponsor provided documentation certifying that acceptable electromagnetic testing (EMC) had been performed and the System was found to be compliant.

7. **Infection Control Studies:**
   The device systems BGM014 and BGM014 Pro are intended for single-patient use only and multi-patient use, respectively. Disinfection efficacy studies were performed by the sponsor using each of the following disinfectants: Clorox Healthcare® Bleach Germicidal and Disinfectant Wipes (EPA Registration Number: 67619-12), Dispatch Hospital Cleaner Disinfectant Towel with Bleach (EPA Reg# 56392-8), Medline Micro-Kill™ Bleach Germicidal Bleach Wipes (EPA Registration Number: 69687-1-37549), Medline Micro-Kill+™ Disinfecting, Deodorizing, Cleaning Wipes with Alcohol (EPA Registration Number: 59894-10). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 730 and 10,950 cleaning and disinfection cycles for single and multi-patient use, respectively. The robustness studies support 3 years of single and multi-patient use. The sponsor has included a warning in the label "These disinfectants were validated separately. Only one disinfectant should be used on the device for the life of the device, as the effect of using more than one disinfectant interchangeably has not been evaluated." Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

8. This device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the submission was received prior to the finalization of the guidance documents.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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