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

A. 510(k) Number:

k173658

B. Purpose for Submission:

New Device

C. Measurand:

Glucose in capillary whole blood from the fingertip

D. Type of Test:

Quantitative, amperometric detection (FAD-GDH)

E. Applicant:

Applied Biomedical LLC

F. Proprietary and Established Names:

Confidence Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345, Glucose test system

2. Classification:

   Class II

3. Product code:

   NBW, System Test, Blood Glucose, Over the Counter

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indication(s) for use below.

2. Indication(s) for use:

   The Confidence Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip. The Confidence Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

   The Confidence Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

   The Confidence Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. The Confidence Blood Glucose Test Strips are for use with the Confidence Blood Glucose Meter to quantitatively measure glucose in capillary whole blood samples drawn from the fingertip

3. Special conditions for use statement(s):

   - For over-the-counter use
   - For single patient use only
   - Not for neonatal use
   - Should not be used for diagnosis of or screening for diabetes mellitus.
   - Not for use in critically ill patients
   - The system should not be used on people who are dehydrated, hypotensive, in shock, or in hyperglycemic/hyperosmolar state, with or without ketosis.
   - A hematocrit that is either very high (above 55%) or very low (below 30%) can cause false results.
   - Only for use with fresh capillary whole blood
   - You may receive wrong results at altitudes above 10,000 ft
   - 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 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:

   Confidence Meter

I. Device Description:

The Confidence Blood Glucose Monitoring System consists of Confidence Blood Glucose Test Strips, the Confidence Meter, and three levels of Confidence Glucose Control Solutions (Levels 1, 2 and 3). To perform a blood glucose measurement, a test strip is inserted in the meter. On inserting the strip, the meter turns on and displays a code, and the user must select a code corresponding to their strip vial using meter's interface. The meter will be ready to apply sample by showing a droplet on the LCD display. On applying blood on the end of the test strip the meter displays the plasma equivalent value (mg/dL) in the blood sample within 10 seconds.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   OneTouch Verio Flex Blood Glucose Monitoring System

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

   k150214

3. Comparison with predicate:

Item	Candidate Device Confidence Blood Glucose Monitoring System	Predicate Device OneTouch Verio Flex Blood Glucose Monitoring System k150214
Indications for Use	Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip as an aid to monitor the effectiveness of diabetes control	Same
Specimen type	Capillary whole blood	Same
Sample site	Fingertip	Same
Test Principle	Amperometry	Same
Enzyme	FAD-GDH	Same

Item	Candidate Device Confidence Blood Glucose Monitoring System	Predicate Device OneTouch Verio Flex Blood Glucose Monitoring System k150214
Altitude	Up to 10,000	Same
Sample Volume	1.2 uL	0.4 uL
Measuring Range	50-600 mg/dL	20-600 mg/dL
Measuring Time	10 seconds	5 seconds
Hematocrit	30%-55%	20%-60%
Calibration Coding	Manual code input	Non-coding

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

FDA Guidance "Self-Monitoring Blood Glucose Test System for Over-the-Counter Use" released on 11 October, 2016.

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

CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

ISO 14971 - Medical devices - Application of risk management to medical devices (2007).

ISO 10993-1 Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process Fourth Edition (2009).

IEC 61010-1 (2nd Edition) - Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 1: General Requirements.

L. Test Principle:

The Confidence Blood Glucose Monitoring System is an electrochemical biosensor using a glucose-oxidizing enzyme, Flavin Adenine Dinucleotide-Glucose Dehydrogenase (FAD-GDH), along with a redox mediator on a disposable test strip (the electrochemical embedded sensor), and a hand-held 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. The resulting glucose value is displayed on the meter in mg/dL for the user.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-Run Precision

The sponsor performed repeatability (within-day) precision studies using venous whole blood samples adjusted to four different glucose concentration levels (51 to 110, 111 to 150, 151 to 250, and 251 to 350 mg/dL). Each glucose concentration level was analyzed in replicates of 10, with 3 test strip lots and 10 meters, for a total of 100 replicates per glucose level per test strip lot (for a total of 300 tests per each glucose level). Results are summarized below:

Glucose Level (mg/dL)	Strip lot	Mean (mg/dL)	SD (mg/dL)	% CV
1 (51-110)	1	59	1.7	2.9
	2	61	1.7	2.8
	3	63	2.2	3.5
	Combined	61	1.9	3.0
2 (111-150)	1	136	2.7	2.0
	2	135	3.6	2.7
	3	132	3.4	2.6
	Combined	134	3.1	2.4
3 (151-250)	1	214	4.9	2.3
	2	220	6.2	2.8
	3	221	4.1	1.9
	Combined	218	5.4	2.3
4 (251-350)	1	320	6.6	2.1
	2	327	6.6	2.0
	3	328	8.5	2.6
	Combined	325	7.2	2.2

Intermediate Precision

Intermediate (day-to-day) precision was evaluated using four levels of glucose control solution (50-100 mg/dL, 111-150 mg/dL, 151-250 mg/dL, and 251-400 mg/dL). Each control level was analyzed on 10 meters using 3 lots of test strips each day for a total of 10 days, giving a total of 100 measurements per lot for a total of 300 measurements for each glucose level. Results are summarized below:

Glucose Level (mg/dL)	Strip lot	Mean (mg/dL)	SD (mg/dL)	% CV
1 (50-110)	1	63	2.2	3.4
	2	59	2.3	4.0
	3	63	2.5	3.9
	Combined	62	2.4	3.8
2 (111-150)	1	139	5.6	4.0
	2	121	4.8	3.9
	3	125	4.6	3.7
	Combined	128	5.0	3.9
3 (151-250)	1	215	8.0	3.7
	2	201	5.7	2.8
	3	215	5.9	2.8
	Combined	210	6.5	3.1
4 (251-400)	1	420	9.0	2.2
	2	402	5.1	1.3
	3	400	7.5	1.9
	Combined	407	7.2	1.8

b. *Linearity/assay reportable range:*

Linearity testing was performed using venous whole blood samples. Twelve samples with the following glucose concentrations were prepared: 40, 48, 74, 151, 204, 261, 361, 419, 473, 522, 553, and 630 md/dL (as established using a laboratory comparator method YSI 2300). Testing was conducted in quadruplicate on three meters using three test strip lots (n=12 tests per glucose concentration). The evaluation yielded the following regression results:

Strip Lot	Slope	Y-Intercept	R^2
1	1.05	4.03	0.999
2	1.01	0.13	0.999
3	1.04	4.1	0.999

The results of the study support the sponsor's claimed glucose measurement range of 50 to 600 mg/dL. If a sample is less than 50 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 and demonstrated to function as intended.

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

Traceability:

The system is traceable to the NIST SRM #917c glucose reference material.

Open and Closed Vial Stability:

Test strip stability was assessed using accelerated and real-time stability studies. Testing protocols and acceptance criteria were reviewed and found to be acceptable. The labeling includes claims that the Confidence Test Strips are stable for 6 months after opening and 12 months unopened when stored between 41-104ºF (5-40ºC) and 10-85% relative humidity.

d. *Detection limit:*

The reportable range for the Confidence Blood Glucose Monitoring System is 50-600 mg/dL. This range was verified by the linearity study (M.1.b).

e. *Analytical specificity:*

Interference studies were performed by spiking endogenous and exogenous substances into venous whole blood. Twenty-eight substances were tested at three glucose levels (50-70, 110-130, and 225-270 mg/dL) in replicates of 10 on each of 3 strip lots per glucose levels yielding thirty replicates per glucose level. Results of spiked samples with potential interferent were compared to samples with zero potential interferent by measurement on the Confidence meter. The compounds at the concentrations listed below did not have significant interference (defined by the sponsor as average bias between spiked and control sample glucose results withitn ± 10% with glucose >100 mg/dL and within 10 mg/dL with glucose <100 mg/dL). The highest concentraitons at which no significant interference was observed are presented in the following table:

Interfering Substance	**Maximum tested concentration with no significant interference (mg/dL)**
Acetaminophen	9.0
Ascorbic acid	5.0
Bilirubin	35.0
Cholesterol (total)	325
Creatinine	20.0
Dopamine HCl	1.5
Ephedrine	0.51
Galactose	15.1
Gentisic Acid	2.5
Glutathione	90.0

Interfering Substance	Maximum tested concentration with no significant interference (mg/dL)
Hemoglobin	210
Ibuprofen	55.2
Isomalt	1.3
L-dopa	3.0
Maltitol	1.1
Maltose	300
Methyl-dopa	1.54
Pralidoxime Iodide (PAM)	20
Salicylate	58
Salicylic acid	60.55
Sodium Chloride (HCl)	457
Tetracycline	1.7
Tolazamide	8.6
Tolbutamide	78.0
Triglycerides	3,000
Uric Acid	10.0
Xylose	50.0

Based on the test results, the sponsor included the following statements in the labeling:

- PAM (Pralidoxime Iodide): Do not test blood glucose during or soon after PAM treatment (>20 mg/dL), it may affect the glucose results.
- Uric acid may cause inaccurate results in certain condition, such as gout or kidney disease, if concentration of the substance is greater than physiological concentration (>10 mg/dL), if you are not sure consult your doctor before using it.
- You should not use this meter if you are taking acetaminophen or acetaminophen containing drugs (e.g. Tylenol™). Acetaminophen in your blood (>9 mg/dL) may cause an inaccurate result.
- Do not test blood glucose during or soon after a xylose absorption test, within 24 hours, it may give falsely elevated results.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device

Not applicable. See User Performance Studies below (section M.3.d) for demonstration of system accuracy in the hands of the intended user.

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 Study

To assess the performance of the Confidence Glucose Monitoring System in the hands of the intended users, the sponsor performed a study with 187 lay user participants who collected and tested samples from their own fingertip. Results were analyzed by comparing blood glucose results obtained by the lay users with the Confidence Glucose Monitoring System against results obtained using a laboratory comparator method (YSI 2300 analyzer). Glucose concentrations in the samples ranged from approximately 60 to 480 mg/dL as measured by the laboratory comparator method. Results are summarized in the tables below:

For glucose concentrations <75 mg/dL			
Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL	
78% (14/18)	100% (18/18)	100% (18/18)	
For glucose concentrations >75 mg/dL			
Within 5 %	Within 10 %	Within 15 %	Within 20 %
59% (100/169)	90% (152/169)	100% (169/169)	100% (169/169)

Results of linear regression analysis:

$y = 1.01x + 0.29$, $R^2 = 0.99$

A readability assessment indicated a Flesch-Kincaid Score of 8 and lower for all instructional materials included with this device.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The sponsor states that American Diabetes Association (ADA) suggests the following ranges of glucose levels for nonpregnant adults without diabetes:

Before a meal: <100 mg/dL
After a meal: < 140 mg/dL

Reference: American Diabetes Association (ADA) Clinical Practice Recommendations: Classification and Diagnosis of Diabetes. Diabetes Care 2018; 41 (Supplement 1):S13-S22.

N. Instrument Name:

Confidence 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?

   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:

   The system is intended to be used with capillary whole blood from the finger. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   The meter is manually coded by the user.

6. Quality Control:

   Confidence Control solutions are aqueous solutions containing glucose and are available at three levels (level 1, level 2 and level 3). Instructions on how to order the control solutions are included in the user manual. The control solution readings are not included in the average of the patient results.

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

1. **Sample Volume Study:**
   To verify the test strip minimum sample volume requirement, fresh venous blood with five volumes (0.6, 0.7, 0.9, 1.2, and 1.5 uL) were tested. Sample concentrations included four glucose concentrations (56, 121, 194, and 302 mg/dL), established using a laboratory comparator method YSI 2300 analyzer, were tested at each volume. Values obtained with the candidate device were compared to values obtained using a laboratory-based comparator method. Results support the claimed minimum sample volume of 1.2 µL. The sponsor provided validation studies demonstrating that with blood volumes below 1.2 µL, the insufficient sample volume error message functioned as intended.

2. **Hematocrit Study:**
   The effect of different hematocrit levels was evaluated using venous whole blood samples with hematocrit levels of 25-60% (25, 30, 35, 40, 45, 50, 55 and 60%) at four levels of glucose (50 – 100, 111-150, 151-250, and 251-400 md/dL). Each sample was tested in replicates of ten using two meters and three test strip lots. Results from the meter were compared to results obtained using a laboratory-based comparator measurement (YSI 2300 analyzer). The evaluation of bias and percent bias relative to values obtained on the YSI 2300 analyzer demonstrate acceptable performance across the claimed hematocrit range of 30-55%.

3. **Altitude Study:**
   The effect of altitude was evaluated using blood samples spiked to four glucose levels (50-110, 111-150, 151-250, and 251-400 mg/dL). The samples were tested at 340 – 10,010 feet above sea level. Results obtained were compared with those obtained with the comparator method (YSI 2300). The results demonstrate acceptable bias to the comparator to support the claims in the labeling at altitudes up to 10,000 feet have no significant effect on blood glucose measurements from the Confidence Blood Glucose Monitoring System.

4. **Operating Conditions:**
   The sponsor performed temperature and humidity studies using venous blood samples with three glucose levels (50-110, 111-150, 151-300). Temperatures ranging from 41°F - 104°F (5-40°C) and relative humidity from 10% to 85% were tested. Meter results were compared

to the YSI 2300 comparator analyzer. Four temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity. The results support the claims in the labeling that the system can be used in conditions of 43°F - 104°F (5-40°C) with relative humidity of 10 to 85%.

5. **Infection Control and Robustness Studies:**
   The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, EPA Certified Germicidal Disposable Cloth (PDI® SUPER SANI-CLOTH®), EPA Reg. No.: 9480-4 (PN1000617). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 200 cleaning and disinfection cycles. The robustness studies support 3 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. **EMC Testing:**
   The sponsor provided appropriate documentation certifying that electromagnetic (EMC) testing was performed and the Confidence Blood Glucose Monitoring System was 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.