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

A. 510(k) Number:

k093745

B. Purpose for Submission:

New Device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose dehydrogenase (FAD)

E. Applicant:

LifeScan Inc.

F. Proprietary and Established Names:

OneTouch Verio Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LFR – Glucose dehydrogenase, glucose	Class II	21 CFR § 862.1345	75-Chemistry
NBW – system, test, blood glucose, over the counter	Class II	21 CFR § 862.1345	75-Chemistry
JJX – Quality Control material	Class I, reserved	21 CFR § 862.1660	75-Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The OneTouch Verio Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The OneTouch Verio Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

   The OneTouch Verio 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 OneTouch Verio Blood Glucose Monitoring System should not be used for the diagnosis of or screen of diabetes or for neonatal use. Alternate site testing should be done only during steady- state times (when glucose is not changing rapidly).

   The OneTouch Verio Test Strips are for use with the OneTouch Verio Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

   The OneTouch Verio Control Solutions are for use with the OneTouch Verio Blood Glucose Meter and Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

3. Special conditions for use statement(s):

   For over-the-counter use.
   Not for neonatal use, not for screening or diagnosis of diabetes mellitus.
   Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.
   Alternate site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.
   AST testing should only be done during steady-state times (when glucose is not changing rapidly).

4. Special instrument requirements:

   OneTouch Verio Blood Glucose Meter

I. Device Description:

The OneTouch Verio Blood Glucose Monitoring System (BMGS) consists of the following devices: OneTouch Verio meter, OneTouch Verio test strips (sold separately), OneTouch Verio control solutions (sold separately), the lancing device for single patient use only, sterile lancets for single patient use only, clear cap (sold separately), carry case, and OneTouch Verio User Guide. Accessories available separately for the OneTouch Verio BGMS include the OneTouch Diabetes Management Software (DMS) and OneTouch interface cable.

Each box of test strips contains two vials of 25 test strips. Each test strip contains the following reagent compositions: flavin adenine dinucleotide-glucose dehydrogenase (from Aspergillus sp.)- 2 U; potassium ferricyanide: 41µg; and other ingredients (buffer, etc.)

Each box of control solutions contain two vials of aqueous control solutions (3.8 mL each): Level 1: medium level contains 0.12% concentrations of glucose (approximately 120 mg/dL) and Level 2: high level contains 0.35% concentrations of glucose (approximately 350 mg/dL).

J. Substantial Equivalence Information:

1. Predicate device name(s):

   OneTouch Ultra 2 Blood Glucose Monitoring System

   OneTouch Select control solutions

2. Predicate K number(s):

   k053529, k072543

3. Comparison with predicate:

Similarities and Differences of the Blood Glucose System		
Item	OneTouch Ultra 2 meter (predicate device), k053529	OneTouch Verio meter (candidate device)
Intended Use/Indications for Use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Setting	at home and in a clinical settings	Only for single patient use at home

Detection method	Amperometry	Same
Enzyme	Glucose Oxidase	Glucose dehydrogenase-flavin adenine dinucleotide
Calibration Coding	User sets calibration code	No coding by user
Power supply	3V Li battery (CR2032×2)	Same
Memory	500 control and glucose	Same
Test range	20 - 600 mg/dL	Same
Hematocrit range	30 - 55%	20- 60%
Sample type	Capillary whole blood	Same
Sample sites	Fingertip, forearm, palm	Same
Sample volume	1 µL	0.4 µL
Sample test time	5 seconds	Same

Similarities and Differences of the control solution		
Item	OneTouch Select Control Solutions (predicated device), k072543	OneTouch Verio Control Solutions (candidate device)
Intended use/Indications for Use	To check that the glucose meter and test strips are working together properly and that the test is performing correctly.	Same
Matrix	Viscosity-adjusted, aqueous liquid	Same
Number of levels	2 levels	Same

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

1. ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
2. FDA Draft Guidance Document-Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems; October 24, 2006.
3. CLSI Guideline, EP6-A Evaluation of the Linearity of Quantitative Analytical Methods; Approved Guideline
4. CLSI Guideline, EP7-A2 Interference Testing in Clinical Chemistry; Approved Guideline- Second edition

L. Test Principle:

The OneTouch Verio Blood Glucose Monitoring System employs flavin adenine dinucleotide-glucose dehydrogenase (GDH-FAD) enzyme chemistry as the standard dry reagent assay for glucose in whole blood. This enzyme assay, with a redox chemical "mediator" reaction, is used to generate an electrical current proportional to the glucose concentration in the blood sample. The system is designed as an amperometric measurement device using current generated from the redox reaction as

the measurable response.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Within-run precision was measured by using heparinized anti-coagulated whole blood at five different glucose concentrations. Each sample was tested on 3 lots of test strips on 30 meters (10 meters per test strip lot). Ten replicates were tested per meter, test strip lot, and glucose concentration, (N=100 per test strip). Results are summarized below:

   Within-run precision for glucose:

Glucose Level	Strip Lot	Mean (mg/dL)	SD (mg/dL)	% CV
40	1	39.4	1.09	2.75
	2	38.7	1.05	2.71
	3	40.0	1.07	2.68
100	1	99.5	1.45	1.46
	2	100.1	1.88	1.87
	3	102.1	1.88	1.84
130	1	126.8	2.58	2.03
	2	125.4	2.54	2.02
	3	126.2	2.09	1.65
200	1	189.4	3.43	1.81
	2	187.9	3.51	1.87
	3	190.5	3.13	1.64
350	1	322.3	6.18	1.92
	2	326.9	6.68	2.04
	3	321.7	7.06	2.19

   Between-day precision was measured by reading two different control materials on 3 lots of test strips, 20 replicates per day for 10 days, (N = 200). Results are summarized below:

Between-day precision for glucose:

Glucose Level	Strip Lot	Mean (mg/dL)	SD (mg/dL)	% CV
120	1	117.5	2.63	2.24
	2	116.0	2.86	2.47
	3	116.1	2.61	2.25
350	1	350.6	7.07	2.02
	2	350.1	7.35	2.10
	3	349.5	7.65	2.19

b. Linearity/assay reportable range:

Linearity study was designed based on CLSI EP6-A guideline. Nine human whole blood samples were drawn into heparinized tubes and spiked to the target analyte levels. 7 target levels were prepared with glucose concentrations ranging from 20 to 600 mg/dL (20, 100, 200, 300, 400, 500, and 600 mg/dL). All samples were tested on 3 lots of test strips in duplicate on the OneTouch Verio meter. All samples were also tested on the YSI 2300 analyzer to generate the expected values. The observed values were plotted against the expected values and an appropriate line fitted by standard linear regression was generated with results summarized below:

Strip Lot	Slope	95% CI slope	Intercept	95% CI intercept	R^2
1	0.947	0.945, 0.95	1.866	1.457, 2.274	0.998
2	0.959	0.957, 0.962	0.567	0.160, 0.974	0.999
3	0.949	0.947, 0.952	1.924	1.531, 2.318	0.999

The results of the study support the sponsor's claim that the glucose assay is linear from 20-600 mg/dL.

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

Traceability: OneTouch Verio Blood Glucose Monitoring System is traceable to the NIST SRM 917b reference material.

Value assignment:

The value assignment of the OneTouch Verio control solutions were determined by an in-house procedure. The control solutions were prepared by gravimetric addition of glucose to achieve target values of 120 ± 5 mg/dL for level 1 and 350 ± 15 mg/dL for level 2 and values were confirmed by a laboratory method. Verification of the control solutions were tested with 100

test strips and 10 meters with each level and the target ranges were set at the following:

Glucose control solution	Target concentration	Acceptable range
Level 1 (medium)	120 mg/dL	120 ± 15% (102-138 mg/dL)
Level 2 (high)	350 mg/dL	350 ± 15% (298-403 mg/dL)

Stability:

Real time stability was performed to assess the shelf-life and open-vial stability of the control solutions and test strips. Stability studies protocol and acceptance criteria were provided and found to be adequate. Unopened control solutions have a 15 month shelf life and are stable for 3 months after first use when stored at 5-30^{o}C (41-86 ^{o}F) . The sponsor claimed that the unopened test strips have a 12 month shelf-life and are stable for 3 months after first use when stored at 5-30^{o}C (41-86 ^{o}F). This information is provided in the labeling of the test strips and control materials.

d. Detection limit:

See linearity study above.

e. Analytical specificity:

Interference study was designed according to CLSI EP7-A2 guideline. 23 common endogenous and exogenous interference substances were evaluated by spiking venous blood with two levels of glucose concentrations (60 mg/dL and 240 mg/dL). The glucose samples were spiked with the potentially interfering compounds and tested on 3 lots of test strips. Bias was calculated as the mean percent difference in glucose reading between the test and control concentration groups. All samples tested showed % bias within ± 10% between the test and the control groups. The sponsor claims no significant interference (≤ 10% difference) for the substances and concentrations shown in the table below:

Compound	Concentration tested up to (mg/dL)
Acetaminophen	11
Bilirubin	40
Gentisic acid	1.8
Uric acid	8.5
Levo-Dopa	3.1

Creatinine	30
Methyl-Dopa	2.5
Tolazamide	5
Dopamine	8
Ascorbate	6
Glutathione	53
Ibuprofen	50
Salicylic acid	60
Tetracycline	10
Tolbutamide	100
Urea	500
Cholesterol	700
Triglyceride	3000
Ephedrine	0.5
Galactose	60
Lactose	20
Maltose	200

The sponsor has the following limitations in their labeling:

"Acetaminophen, uric acid and ascorbic acid (vitamin C) (when occurring in blood at normal or at high therapeutic concentration) do not significantly affect results. However, abnormally high concentration in blood may cause inaccurately low results."

"The OneTouch Verio Blood Glucose Monitoring System should not be used by patients within 24 hours of receiving a D-xylose absorption test as it may cause inaccurately high results."

"Critically ill patients should not be tested with blood glucose meters. Test results can be falsely low if the patients is severely dehydrated, in shock, or in hyper-osmolar state (with or without ketosis)."

Hematocrit Study - The sponsor performed hematocrit studies using five different hematocrits (Hct) (19, 30, 40, 50 and 61%) levels across the glucose measuring range (20-600 mg/dL). At each hematocrit level, 4 samples at glucose concentration of 30, 65, 240, and 450 mg/dL were tested against the YSI method. 3 lots of test strips were tested on 12 meters and the values were compared to the YSI method and the nominal hematocrit level (40%). Results are summarized below:

Glucose (mg/dL)	Hct (%)	One Touch Verio result	YSI result	% bias between OneTouch Verio and YSI	% bias vs. nominal Hct
30	19	32.4	33.3	-0.98	-1.25
	30	32.4	32.8	-0.37	-1.22
	40	33.6	32.9	0.68	0
	50	35.8	32.5	3.31	2.21
	61	38.1	32.3	5.81	4.46
65	19	64.8	66.1	-1.25	-0.93
	30	61.9	63.3	-1.34	-1.02
	40	65.8	66.2	-0.32	0
	50	69.1	66.2	2.95	3.28
	61	70.8	66.3	4.50	4.82
240	19	241.0	238.3	1.15	3.23
	30	232.0	235.4	-1.43	0.65
	40	231.4	236.3	-2.08	0
	50	232.6	239.0	-2.70	-0.62
	61	223.7	237.2	-5.71	-3.63
450	19	438.5	440.1	-0.37	2.18
	30	431.1	440.8	-2.20	0.34
	40	432.3	443.6	-2.55	0
	50	435.5	447.6	-2.70	-0.15
	61	424.8	450.7	-5.77	-3.22

The sponsor claimed that hematocrit values between 20% to 60% do not significantly affect the glucose results.

Altitude Study - A study was conducted to evaluate the effect of altitude on the OneTouch Verio BGMS. 3 lots of test strips were tested on 16 meters using blood from three donors at three glucose concentrations (70, 240, and 450 mg/dL) at three altitude levels (3000, 6000, and 10,000 feet), and sea level (0 feet) as a control. Testing was performed in a hyperbaric chamber. Each venous blood sample was also tested by the YSI 2300 analyzer. The meter readings obtained were compared to the YSI method and the percent bias was determined at each level against the YSI results. Bias was within ± 10% for all three altitude levels tested. Based on the data, the sponsor claims that the OneTouch Verio BMGS can be used at altitude up to 10,000 feet.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

System accuracy study was performed according to the ISO 15197 document using 100 participants from a diabetic clinic. A trained healthcare professional (HCP) collected fingersticks on each participant. Capillary samples were collected and measured on the YSI 2300 analyzer (reference method) and from the same fingersticks, the OneTouch Verio BGMS was tested in duplicate with 3 lots of test strips. The range of glucose values for the fingerstick samples was 36-465 mg/dL. In order to obtain sufficient samples in the lowest and highest concentration intervals, 22 capillary samples were altered. Samples that were <80 mg/dL and >321 mg/dL were contrived samples and samples between 80 to 321 mg/dL were natural samples. Regressions analysis results are summarized below:

Regressions between OneTouch Verio BGMS results and the YSI method for the fingersticks samples:

Strip Lot	Linear regressions	95% CI slope	95% CI intercept	R^2	N
1	Y=0.999X – 0.785	0.986, 1.013	-3.603, 2.032	0.990	200
2	Y=0.997X – 0.383	0.981, 1.012	-3.580, 2.813	0.988	200
3	Y=0.987X + 0.558	0.971, 1.002	-2.647, 3.762	0.987	200
Combined	Y=0.994X – 0.204	0.986, 1.003	-1.971, 1.564	0.988	600

Based on the ISO Standard 15197 document, how well the OneTouch Verio BGMS when HCP tested the fingersticks and contrived samples as compared with the YSI method is shown in the tables below:

System accuracy results for glucose concentration <75 mg/dL

Strip Lot	Within±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
1	25/32 (78.1%)	30/32(93.8%)	32/32 (100%)
2	27/32 (84.4%)	31/32 (96.9%)	32/32 (100%)
3	26/32 (81.3%)	31/32 (96.9%)	32/32 (100%)
Combined	78/96 (81.3%)	92/96 (95.8%)	96/96 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Strip Lot	Within±5%	Within± 10%	Within± 15%	Within±20 %
1	111/168 (66.1%)	155/168 (92.3%)	167/168 (99.4%)	168/168 (100%)
2	102/168 (60.7%)	150/168 (89.3%)	167/168 (99.4%)	168/168 (100%)
3	105/168 (62.5%)	159/168 (94.6%)	165/168 (98.2%)	167/168 (99.4%)
Combined	318/504 (63.1%)	464/504 (92.1%)	499/504 (99.0%)	503/504 (99.8%)

A user performance study was performed to compare the lay user self-test results (with fingertip) and the YSI method. Study was performed in two clinical sites with 156 subjects, including 51% male and 49% female. 3 lots of test strips were used and each lay user tested two lots of strips randomly. Only the first test strip results were used for the data analysis. The range of glucose values for the fingerstick samples was 37.7-443.3 mg/dL. Linear regressions analysis results are summarized below:

Regressions between lay user's fingerstick results and the YSI method:

Tester	Linear regressions	95% CI slope	95% CI intercept	R^2	N
Lay user vs. YSI	Y=0.96X + 3.16	0.96, 1.00	0.04, 6.27	0.98	156

Based on the ISO Standard 15197 document, how well the OneTouch Verio BGMS when lay user tested themselves as compared with the YSI method is shown in the tables below:

System accuracy results for glucose concentration <75 mg/dL

Within±5 mg/dL	Within± 10mg/dL	Within±15mg/dL
21/28 (75%)	28/28(100%)	28/28(100%)

System accuracy results for glucose concentration ≥75 mg/dL

Within±5%	Within ± 10%	Within ± 15%	Within±20%
68/128 (53.1%)	115/128 (89.8%)	127/128 (99.2%)	128/128 (100%)

Total accuracy agreement: 100% (156/156) of all the individual glucose results fall within ±15 mg/dL of the YSI results of glucose concentration <75 mg/dL and within ±20% of the YSI results of glucose concentration ≥75 mg/dL.

Alterative testing sites (AST) for blood glucose measurement were evaluated with 164 layusers during a user performance study. Testing was performed by the lay user using the forearm and palm (thenar and hypothenar regions) to show comparable performance at times of steady state conditions with the fingertip glucose results measured with the YSI method. The range of glucose values for these samples was 48.9-443.5 mg/dL (by the finger). Two subjects did not obtain a palm result and 12 subjects did not obtain a forearm result due to error messages or insufficient blood. One result from the forearm was excluded because the result was marked as a control result. The linear regressions were summarized below:

AST sites	Linear regressions	R^2	N
Forearm vs. YSI	Y=0.98X + 4.53	0.97	151
Palm vs. YSI	Y=0.97X + 4.49	0.95	162

Based on the ISO Standard 15197 document, how well the alternative testing by lay users compared with the YSI method is shown in the tables below:

1. Lay user test results of the **forearm** when compared to the YSI method:

System accuracy results for glucose concentration <75 mg/dL

Within±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/7 (57.1%)	6/7 (85.7%)	7/7 (100%)

System accuracy results for glucose concentration ≥75 mg/dL

Within±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	Within±20 mg/dL
66/144 (45.8%)	110/144 (76.4%)	127/144 (88.2%)	138/144 (95.8%)

2. Lay user test results of the **palm** when compared to the YSI method:

System accuracy results for glucose concentration <75 mg/dL

Within±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
6/8 (75.0%)	8/8 (100%)	8/8 (100%)

System accuracy results for glucose concentration ≥75 mg/dL

Within±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	Within±20 mg/dL
80/154 (51.9%)	132/154 (85.7%)	146/154 (94.8%)	150/154 (97.4%)

b. Matrix comparison:

None. Only capillary whole blood samples are acceptable matrix.

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):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Expected blood glucose results for non-pregnant people without diabetes were cited from the literature[1] and presented in the labeling as follows:

Fasting: <100 mg/dL
2 hours after meal: < 140 mg/dL

[1]American Diabetes Association, Position Statement, Diagnosis and Classification of Diabetes Mellitus, Diabetes Care 31:555-560, 2008

N. Instrument Name:

OneTouch Verio meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.4 uL.

   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 glucose test is intended to be used with capillary whole blood from the finger, palm, and forearm only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   There is no calibration required for the OneTouch Verio meter by the user. The meter is plasma-calibrated.

6. Quality Control:

   Glucose control solutions at two different concentrations can be run with this device. The meter has an algorithm to automatically recognize the control solutions to prevent control results from being stored in the internal memory as patient result. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results. An acceptable range for each control level is printed on the control solutions vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. A usability study was performed to assess the readability of the labeling by recruiting 100 lay users (aged 18-70 yrs old) who were provided with the test kit containing labeling for the US market. Participants varied in age, education, country of origin, and were about evenly divided between men and women. These lay users also completed a questionnaire to response to whether the device is easy to use and the Instructions for use were written in a way that makes it easy to use. The majority of the users responded that the device is very easy to use.

2. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (User Guide, test strip package insert and control solution package insert) were written at the 8^{th} grade level.

3. Customer service is available 24/7, 365 days a year. Toll free phone number is 1-800-227-8862 for customer support.

4. A sample volume study was performed to verify the test strip sample volume requirement and the test strip fill error requirement established for the OneTouch Verio BGMS. Three lots of test strips were tested using blood from three donors, each adjusted to a glucose concentration of 65 and 450 mg/dL. Blood at each concentration was applied to strips at five target sample volumes of 0.25, 0.3, 0.35, 0.4 and 0.45 µL. Protocols and acceptance criteria were provided and found to be acceptable. The sponsor concluded that sample volume of ≥0.4 µL produced accurate results and samples <0.4 µL give an error code.

5. Temperature and humidity operating conditions were evaluated for temperatures ranging from 5°C to 45°C and relative humidity from 10% to 90%. Protocol and

acceptance criteria were provided and found to be acceptable. The results supported the sponsor's claimed operating temperature from 6°C to 44°C(43°F to 111°F) and relative humidity range from 10% to 90%.

6. EMC testing was evaluated and certified by CSA International and a letter of attestation was issued to LifeScan on December 3, 2008.

7. The device is intended for single-patient use only. Clorox Germicidal Wipes with EPA registration # 67619-12 was validated demonstrating complete inactivation of live virus for use with the meter and lancing device. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 2879 cleaning cycles and 412 disinfection cycles designed to simulate 4 years of device use.

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.