



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

I Background Information:

A 510(k) Number

K193475

B Applicant

LifeScan Europe GmbH

C Proprietary and Established Names

OneTouch Verio Reflect Glucose 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

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Capillary whole blood glucose

C Type of Test:

Quantitative Amperometric assay (FAD-Glucose Dehydrogenase)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The OneTouch Verio Reflect Blood Glucose Monitoring System is composed of the OneTouch Verio Reflect Meter and OneTouch Verio Test Strips. The OneTouch Verio Reflect 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. The OneTouch Verio Reflect Blood Glucose Monitoring System is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single person and should not be shared. The system should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

C Special Conditions for Use Statement(s):

- OTC - Over The Counter
- For in vitro diagnostic use
- The OneTouch Verio Reflect Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.
- The system is not to be used for the diagnosis of or screening of diabetes or for neonatal use.
- The system is not for use on critically ill patients, patients in shock, and severely dehydrated patients or hyperosmolar patients.
- Do not use the OneTouch Verio Reflect System for alternate site testing (AST).
- Should not be used at altitude above 10,000 feet as there may be an adverse effect on test results.
- A hematocrit (percentage of your blood that is red blood cells) that is either very high (above 60%) or very low (below 20%) can cause false results. Talk to your healthcare professional if you don't know your hematocrit level.
- 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 the 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

D Special Instrument Requirements:

OneTouch® Verio Reflect Blood Glucose Meter

IV Device/System Characteristics:

A Device Description:

The OneTouch Verio Reflect Blood Glucose Monitoring System consists is composed of the OneTouch Verio Reflect Meter and the OneTouch Verio Test Strips (sold separately), owner's manual, OneTouch Verio Level 3 and Level 4 Control Solutions (available separately), and the OneTouch Delica Plus Lancing Device and Sterile lancets. The OneTouch Verio Test Strips were previously cleared in the predicate, k150214.

B Principle of Operation:

The OneTouch Verio Reflect Blood Glucose Monitoring System uses electrochemical methodologies. The system quantitatively measures blood glucose levels using an amperometric method that employs flavin adenine dinucleotide-glucose dehydrogenase (GDH-FAD) enzyme chemistry as the standard dry reagent assay for glucose in whole blood. This enzymatic assay is coupled with a redox (reduction-oxidation) chemical "mediator", to generate an electrical current proportional to the glucose concentration in the blood sample. The resulting signal is converted by the meter into a readout displayed on the meter.

C Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

1. Instrument Name:

OneTouch Verio Reflect Blood Glucose Monitoring System

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:

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

4. Calibration:

The meter does not require calibration or coding by the user. The meter is automatically coded.

5. Quality Control:

OneTouch Verio Level 3 and Level 4 Control Solutions are used with the OneTouch Verio Reflect Blood Glucose Monitoring System. The control solutions are aqueous solutions that can be purchased separately. Recommendations on when to perform a control solution test are provided in the labeling. The meter has Control Test setting for the user to select when performing the test. Control solution results are stored in the meter and not included in the patient results averages. Acceptable range for each control level is provided on the test strip vial label. The user is cautioned not to use the meter if the control results fall outside these ranges.

V Substantial Equivalence Information:

A Predicate Device Name(s):

OneTouch Verio Flex Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

K150214

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K193475</u>	<u>K150214</u>
Device Trade Name	OneTouch Verio Reflect Blood Glucose Monitoring System	OneTouch Verio Flex Blood Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	To be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control.	Same
Detection Method	Amperometric	Same
Enzyme	FAD-Glucose Dehydrogenase	Same

General Device Characteristic Differences		
Result Analysis Features	Features to enable tagging of results, averaging and graphing of results over time, providing trend graphs and patterns	None
User Interface Screen	Menu driven with text and icon-based information	No Menu or text. Graphics to instruct user to apply sample to strip

VI Standards/Guidance Documents Referenced:

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use
Guidance for Industry and Food and Drug Administration Staff. October 11, 2016

EP05-A3 Clinical Laboratory Improvement Amendment (CLIA). Evaluation of Precision of Quantitative Measurement Procedures. October 2014

EP06-A – CLSI -Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach. Version A. April 2003

EP07 – CLSI. Interference Testing in Clinical Chemistry. 3rd Edition. April 2008

14971 – ISO. Medical Devices Application of Risk Management to Medical Devices. March 2007

International Electrotechnical Commission (IEC). 62366-1. Medical Devices Part 1: Application of Usability Engineering to Medical Devices. February 2015

IEC. 60601-1-11 Edition 2.0 Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment 2015-01

IEC. 62304. Edition 1.1 2015-06 Medical Device Software. Software life cycle processes – 2015

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability/Within-Run Precision

The sponsor performed within-run precision studies using venous whole blood adjusted to 5 glucose levels (approximately 40, 90, 130, 200, and 350 mg/dL) with 3 test strip lots on 30 meters (10 meters/lot of strips). Each sample was tested in 10 replicates per meter, per strip lot, and glucose concentration resulting in a total of 300 tests performed per glucose level. Results are summarized below:

Target Glucose (mg/dL)	Strip Lot	Average Glucose (mg/dL)	SD (mg/dL)	CV (%)
40	1	36.9	1.06	2.86
	2	39.3	0.86	2.19
	3	34.2	1.19	3.49
	Combined	36.8	1.05	2.84
90	1	88.3	2.66	3.01
	2	90.4	2.01	2.23
	3	90.6	2.65	2.93
	Combined	89.7	2.46	2.74
130	1	133.7	4.80	3.59
	2	137.1	3.29	2.40
	3	127.7	3.99	3.12
	Combined	132.8	4.07	3.07
200	1	208.6	5.59	2.68
	2	206.7	4.19	2.03
	3	205.1	6.56	3.20
	Combined	206.8	5.53	2.68
350	1	375.5	9.85	2.62
	2	365.9	11.42	3.12
	3	364.8	11.19	3.07
	Combined	368.7	10.84	2.94

Intermediate precision

Intermediate precision was evaluated using five glucose control solutions with glucose concentration ranges of: 30-50, 51-110, 111-150, 151-250, 251-400 mg/dL . Each glucose level was tested using 30 meters and three test strip lots over 10 days with 2 replicates per

meter, per control solution, per strip lot, per day. Results are summarized below:

Glucose Target (mg/dL)	Strip Lot	Average Response (mg/dL)	SD (mg/dL)	CV (%)
30 – 50	1	37.80	0.89	2.35
	2	37.41	0.90	2.41
	3	38.03	1.00	2.63
	Combined	37.74	0.93	2.47
51 – 110	1	69.61	1.39	1.99
	2	68.71	1.43	2.08
	3	68.70	1.38	2.00
	Combined	69.00	1.40	2.02
111 -150	1	119.44	2.01	1.69
	2	117.83	2.14	1.81
	3	118.68	2.54	2.14
	Combined	118.65	2.24	1.89
151 - 250	1	202.68	3.76	1.86
	2	198.50	3.78	1.90
	3	200.42	3.54	1.77
	Combined	200.53	3.70	1.84
251 - 400	1	347.28	7.53	2.17
	2	344.53	6.94	2.01
	3	348.42	8.43	2.42
	Combined	346.74	7.66	2.21

2. Linearity:

Linearity was evaluated using venous whole blood adjusted to eleven glucose levels at 19.63, 42.85, 63.86, 97.43, 145.63, 198.63, 296.50, 400.38, 500.38, 581.25, 688.38 as measured by comparator method, YSI 2300. The meter results, using 3 test strip lots, were compared with the values obtained from the comparator method (YSI 2300). The results from the regression analysis are summarized below:

Lot 1: $y = 1.029x - 1.883$, $R^2 = 0.998$

Lot 2: $y = 1.013x - 2.562$, $R^2 = 0.999$

Lot 3: $y = 1.027x - 2.747$, $R^2 = 0.999$

The results of the study support the sponsor's claimed glucose measurement range of 20 to 600 mg/dL. Data from the bench studies and software verification studies were provided to demonstrate that if a sample is less than 20 mg/dL, the result is flagged by the meter and a warning error "Extreme Low Glucose – Below 20 mg/dL – Treat Low" is displayed, as intended. If a sample result is more than 600 mg/dL, the result is flagged by the meter and a warning error "Extreme High Glucose – Above 600 mg/dL" is displayed, as intended.

3. Analytical Specificity/Interference:

Interference studies were performed by altering venous whole blood to achieve three glucose concentration levels (60, 120 and 260 mg/dL). Each of these samples was divided into a test pool and a control pool and each of 32 potential endogenous and exogenous interfering substances was added to the test pool. Each potential interferent was tested on three lots of test strips. The highest tested concentrations at which no significant interference was observed (defined by the sponsor as within ± 6.04 mg/dL at glucose levels < 80 mg/dL and within $\pm 7.38\%$ at glucose levels ≥ 80 mg/dL when comparing the test sample relative to the control sample) with the OneTouch Verio Reflect Glucose Monitoring System are presented in the following table:

Potential Interfering Substance	Maximum Tested Concentration with no Significant Interference (mg/dL)	Potential Interfering Substance	Maximum Tested Concentration with no Significant Interference (mg/dL)
Acetaminophen	21.89	Maltitol	0.15
Ascorbic Acid	7.37	Maltose	482
Bilirubin (conjugated)	25.95	Mannitol	1801.72
Bilirubin (unconjugated)	41.94	M-Dopa (Methyl-Dopa)	2.2
Cholesterol	838.7	Pralidoxime Iodide (PAM)	N/A
Creatinine	31.29	Salicylic Acid (Salicylate)	61.12
Dopamine	0.12	Sodium	415
Galactose	62	Sorbitol	0.15
Gentisic Acid	1.85	Tetracycline	1.52
Glutathione	40.41	Tolazamide	10.64

Potential Interfering Substance	Maximum Tested Concentration with no Significant Interference (mg/dL)	Potential Interfering Substance	Maximum Tested Concentration with no Significant Interference (mg/dL)
Hemoglobin	1108.95	Tolbutamide	75
Ibuprofen	51.49	Triglycerides	3453.74
Icodextrin	1241.72	Urea	287.54
Isomalt	0.15	Uric Acid	30.13
Lactitol	0.15	Xylitol	0.15
L-Dopa (Levo-Dopa)	1.35	Xylose	N/A

The sponsor has included the following statements in their labeling:

The OneTouch Verio Reflect Blood Glucose Monitoring System should not be used within 24 hours of receiving a D-xylose absorption test as it may cause inaccurately high glucose results with your meter.

Do Not use the OneTouch Verio Reflect Blood Glucose Monitoring System if you are being treated for organophosphate poisoning with Pralidoxime (PAM) as it may cause inaccurate glucose results with your meter.

4. Assay Reportable Range:

The assay reportable range of 20-600 mg/dL is supported by the Linearity assay above (Section VII.A.2).

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

Traceability

The system is traceable to the NIST SRM #917 glucose reference material. A method comparison study was performed using the candidate device and the YSI 2300 STAT PLUS glucose analyzer as the comparator method (see Section VII.C.3. below).

Test Strip stability:

The OneTouch Verio Reflect Blood Glucose test strip stability was assessed using accelerated and real time stability studies. Protocols and acceptance criteria were reviewed and found acceptable. The labeling includes claims that the test strips are stable for 6 months after opening and 22 months unopened when stored between of 41°F to 86°F (2°C-30°C) and between 10-90% relative humidity.

6. Detection Limit:

See the linearity study above, section VII.A.2.

7. Assay Cut-Off:

Not applicable.

8. Accuracy (Instrument):

Not applicable.

9. Carry-Over:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

See Lay-user study below, Section VII.C.3.

2. Matrix Comparison:

Not applicable.

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):

Lay-User Comparison Study:

To assess the performance of the OneTouch Verio Reflect Glucose Monitoring System in the hands of the intended users, the sponsor performed studies in multiple sites with results from 354 English speaking participants. The users were responsible for obtaining their own fingertip capillary sample and performing a blood glucose test using only the instruction from the product labeling and 3 lots of test strips. Results were analyzed by comparing blood glucose results from the OneTouch Verio Reflect Glucose Monitoring System obtained by the lay user against the YSI 2300 comparator value. The samples ranged from 46 to 563 mg/dL as measured by the comparator method with 11 subjects with glucose less than 80

mg/dL and 62 subjects with glucose greater than 250 mg/dL. The 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	Within ± 20 mg/dL
4/10 (40%)	8/10 (80%)	10/10 (100%)	10/10 (100%)

For glucose concentrations ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
218/344 (63.4%)	327/344 (95.1%)	342/344 (99.4%)	344/344 (100%)

Combined glucose concentrations across the measuring range:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
222/354 (62.7%)	333/354 (94.1%)	351/354 (99.2%)	354/354 (100%)

Readability:

A Flesch-Kincaid readability assessment was conducted, and the results demonstrated that the Owners Booklet, Test Strip Insert and Control Solution Insert, were written at an 8th grade reading level or less.

Accuracy at Extreme Glucose Study:

A study to evaluate the performance of the OneTouch Verio Reflect Blood Glucose Monitoring System in the extreme lower and upper ends of the claimed glucose measuring range was performed using 100 capillary samples with 50 altered to achieve glucose below 80 mg/dL and 50 greater than 250 mg/dL as measured by the comparator method, YSI 2300. Samples were tested on 3 test strip lots and compared to results obtained on the YSI 2300 analyzer. Results are summarized below:

For glucose concentrations < 80 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
31/50(62%)	50/50 (100%)	50/50 (100%)	50/50(100%)

For glucose concentrations > 250 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
46/50 (92%)	50/50 (100%)	50/50 (100%)	50/50(100%)

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The sponsor has included the following information about expected glucose within their labeling:

Expected blood glucose levels for non-pregnant people without diabetes¹:

<u>Time</u>	<u>Range, mg/dL</u>
Fasting	Less than 100
2 hours after meals	Less than 140

¹American Diabetes Association, Standards of Medical Care in Diabetes, Diabetes Care Vol. 41, Supplement 1, S1-S2, January 2018.

F. Other Supportive Instrument Performance Characteristics Data:

1. Hematocrit Study:

To evaluate the effect of hematocrit on the OneTouch Verio Reflect Blood Glucose Monitoring System, venous blood samples were adjusted to hematocrit levels of 20%, 25%, 30%, 35%, 42%, 50%, 55%, and 60%. Each hematocrit level was adjusted to achieve five glucose levels (approximately 45, 65, 130, 200, 350 mg/dL). Each sample was tested using 10 OneTouch Verio Reflect meters and three OneTouch Verio Test Strip lots and the results were compared to those obtained from the YSI 2300 comparator method. The percent biases relative to the YSI demonstrated acceptable performance to support the claimed hematocrit range of 20 to 60%.

2. Altitude Testing:

Altitude testing was previously established in k150214 to support the claims in the labeling that the system can be used at altitudes of up to 10,000 ft.

3. Operating Conditions study:

The effect of temperature and relative humidity on the OneTouch Verio Reflect Blood Glucose Monitoring System was evaluated using venous whole blood samples from 3 donors adjusted to 5 glucose concentrations (approximately 65, 150, 240, 350, and 450 mg/dL.) Testing was conducted under the following temperature and relative humidity (RH) combinations: (41°F(5°C)/50%RH, 48°F(9°C)/10%RH, 48°F(9°C)/50%RH, 48°F(9°C)/90%RH, 72°F(22°C)/10%RH, (nominal/control laboratory condition of 72°F(22°C)/50%RH), 72°F (22°C)/90%RH, 106°F(41°C)/10%RH), 106°F(41°C)/50%RH), 106°F(41°C)/90%RH), 113°F(45°C)/50%RH). Samples were tested under each temperature/humidity condition using 6 meters and 3 lots of test strips. The results support

the claims in the labeling that the OneTouch Verio Reflect Blood Glucose Monitoring System can be used in conditions of 43-111°F (6-44°C) and 10 %RH to 90 %RH.

4. Sample Volume Study:

The sponsor performed a study to support the claimed minimum sample volume of 0.4 µL for the Verio Reflect Blood Glucose Monitoring System. Venous whole blood samples with 3 glucose concentrations (approximately 60, 110 and 225mg/dL) were tested at 4 sample volumes (0.2, 0.3, 0.4 and 0.5 µl) using 3 lots of test strips. Values obtained were compared to the comparator YSI 2300 and results support the claimed minimum sample volume of 0.4 µl for the system. The meter has an error message displayed if enough blood is not added to the test strip. This feature was validated and was shown to function as intended.

5. Flex Studies

Drop testing, vibration testing, intermittent sampling, sample perturbation, and testing with used test strips were completed. The testing performed demonstrated that the device is robust to these common use scenarios, and that the appropriate error messages are returned to the user if one of the situations has occurred.

6. Infection Control studies

The OneTouch Verio Reflect Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies were performed on the meter materials by an outside commercial laboratory, demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant Clorox Germicidal Wipe (EPA Registration Number 67619-12). Robustness studies were also performed by the sponsor using the OneTouch Verio Reflect System demonstrating that there was no change in the performance of the system or in the external materials of the meter after 209 cleaning and disinfection cycles and 418 additional cleaning cycles using the chosen disinfectant. The robustness studies were designed to simulate cleaning and disinfecting over the 4-year single-patient use life of the meter. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. Electrical Safety and EMC testing:

The sponsor provided documentation certifying that acceptable electrical safety and electromagnetic compatibility (EMC) testing had been performed and the system was found to be compliant.

8. Test Strip Lot Release Protocol:

The test strip lot release protocol and acceptance 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.