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

A. 510(k) Number:

k110637

B. Purpose for Submission:

New Device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose dehydrogenase (FAD)

E. Applicant:

LifeScan Europe, a Div. of Cilag GmbH International

F. Proprietary and Established Names:

OneTouch® Verio™ IQ 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

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:
   The One Touch® Verio™ IQ 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 One Touch® Verio™ IQ Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

   One Touch® Verio™ IQ 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 One Touch® Verio™ IQ Blood Glucose Monitoring System is not to be used for the diagnosis of or screening of diabetes, or neonatal use.

   The OneTouch® Verio™ Test Strips are for use with the OneTouch® Verio™ IQ Blood Glucose Meter to quantitatively measure glucose drawn from the fingertips.

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.

4. Special instrument requirements:

   OneTouch® Verio™ IQ Meter

I. Device Description:

The OneTouch® Verio™ IQ Blood Glucose Monitoring System consists of the following components: OneTouch® Verio™ IQ Blood Glucose Meter (with rechargeable battery included), OneTouch® Verio™ Test Strips, OneTouch ® Delica ™Lancing Device, Sterile Lancets, Carrying case, AC adaptor (wall charger), mini USB cable, and OneTouch® Verio™ IQ product labeling. Accessories available separately for the OneTouch® Verio ™ BGMS include the OneTouch® Diabetes Management Software (DMS), OneTouch® Verio™ Level 3 (mid) and Level 4 (high)Control Solutions, and OneTouch® Verio™ test strips.

1. Predicate device name(s):

   OneTouch®Verio™ IQ Blood Glucose Monitoring System

2. Predicate K number(s):

k093745

3. Comparison with predicate:

Similarities and Differences of the Blood Glucose System		
Item	OneTouch® Verio™ Blood Glucose Monitoring System (predicate device), k093745	OneTouch® Verio™ IQ Blood Glucose Monitoring System (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
Testing sites	the finger, forearm and palm	Fingertips
Setting	Only for single patient use at home	Same
Detection method	Amperometry	Same
Enzyme	Glucose dehydrogenase-flavin adenine dinucleotide (GDH-FAD)	Same
Calibration Coding	No user coding required	Same
Power supply	3V Li battery (CR2032×2)	3.7 volt Lithium Ion Polymer rechargeable battery
Memory	500 control and glucose	750 control and blood glucose results
Test range	20 - 600 mg/dL	Same
Hematocrit range	20 – 60%	Same
Sample type	Capillary whole blood	Same
Sample sites	Fingertip, forearm, and palm	Fingertip
Sample volume	0.4 µL	Same
Sample test time	5 seconds	Same

Similarities and Differences of the control solution		
Item	OneTouch® Verio™ Blood Glucose Monitoring System (predicate device), k093745	OneTouch® Verio™ IQ Blood Glucose Monitoring System (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	Same

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

1. ISO 15197: 2003 (E), In vitro diagnostic test systems - Requirements for In Vitro Whole Blood Glucose.
2. EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
3. EP7-A2: Interference Testing in Clinical Testing; Approved Guideline – Second Edition

L. Test Principle:

The OneTouch Verio IQ Blood Glucose Monitoring System uses 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 for the redox reaction as the measureable response.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Within-run precision was measured by using whole blood with sodium heparin as the anti-coagulant 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:

Glucose Level (mg/dL)	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
40	1	42.3	1.21	2.85
	2	42.3	1.16	2.74
	3	42.6	1.27	2.99
100	1	97.2	2.00	2.06
	2	97.0	1.76	1.81
	3	98.1	1.76	1.79
130	1	130.1	2.48	1.91
	2	129.4	2.58	2.00
	3	131.3	2.39	1.82
200	1	195.2	3.80	1.95
	2	196.1	4.04	2.06
	3	197.2	4.03	2.05
350	1	331.5	6.91	2.09
	2	328.8	8.59	2.61
	3	330.8	6.51	1.97

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

Glucose Level (mg/dL)	Strip Lot	Mean (mg/dL)	SD (mg/dL)	% CV
50	1	49.8	1.68	3.38
	2	50.3	1.64	3.27
	3	50.8	1.84	3.62
120	1	116.9	2.38	2.04
	2	116.8	2.37	2.03
	3	117.7	2.59	2.20
350	1	343.6	7.93	2.31
	2	339.9	8.00	2.35
	3	343.6	8.53	2.48

b. Linearity/assay reportable range:

The linearity study was designed following CLSI EP6-A guideline. Nine human venous whole blood samples were drawn and spiked to target analyte levels. Eight target levels were prepared with glucose stock solutions to glucose concentrations ranging from 20 to 600 mg/dL. All samples were tested on 3 lots of test strips in duplicate using one the OneTouch Verio IQ 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	Intercept	R^2
1	0.939	3.44	0.998
2	0.932	3.60	0.998
3	0.939	3.77	0.998

The sponsor's claimed range for the glucose assay is linear from 20-600 mg/dL.

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

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

Controls and Test Strips previously cleared: See k093745 for traceability, stability, and expected value information. OneTouch Verio Control solutions submitted for k093745 are the same control solution material and same concentrations as the control material used for this current submission k110637. Due to changes in labeling regulations, these control materials have been renamed for this current submission k110637.

OneTouch Verio Control Solutions:

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 ± 15 mg/dL for level 3 and 350 ± 15 mg/dL for level 4 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 3 (medium)	120 mg/dL	120 ± 15% (102-138 mg/dL)
Level 4 (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). 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 whole blood with two levels glucose concentrations (65 mg/dL and 240 mg/dL).

The glucose samples were spiked with the potentially interfering compounds and tested on 3 lot of test strips. Each glucose concentration has five different concentrations of the interference substances. The labelling states that elevated concentrations of acetaminophen, ascorbic acid, uric acid, tolazamide, and xylose may affect the blood glucose results. Bias was calculated as the difference between the test and control concentration groups. The sponsor claims no significant interference for the substances and concentrations shown in the table below:

Endogenous Compounds	High Normal/High Therapeutic Level (mg/dL)	Concentration tested up to (mg/dL)
Ascorbic Acid	2.0	6.0
Bilirubin	1.2	40
Cholesterol	300	700
Creatinine	1.5	5
Glutathione	1.6	92.2

Triglycerides	250	3000
Urea	21	257.7
Uric Acid	8	24

Exogenous Substances	High Normal/High Therapeutic Level (mg/dL)	Concentration tested up to (mg/dL)
Acetaminophen	3	20.0
Dopamine	0.03	0.09
Ephedrine	0.01	0.5
Gentisic Acid	0.6	1.8
Ibuprofen	7.0	50
Levo dopa	0.3	4
Methyl dopa	0.75	1.5
Salicylate	30	60
Tetracycline	0.5	1.5
Tolazamide	1.6	15
Tolbutamide	11	64

Sugar Alcohols	High Normal/High Therapeutic Level (mg/dL)	Concentration tested up to (mg/dL)
Lactose	0.5	20
Galactose	14	59.5
Maltose	120	200
Xylose	60	100

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

System accuracy study:

This study was designed following ISO 15197:2003(E) using 100 participants from a diabetic clinic. A trained healthcare professional collected fingersticks on each participant. Capillary samples were collected and measured on the YSI 2300 analyzer (reference method) and from the same fingersticks; the OneTouchVerio IQ BGMS was tested in duplicate using three different test

strip lots. The range of samples tested was 33 – 541 mg/dL. In order to obtain sufficient samples in the lowest and highest concentration intervals, 18 capillary samples were altered. Samples that were <80 mg/dL and > 301 mg/dLwere contrived samples and samples between 80 to 300 mg/dL were natural samples. Regression analysis is summarized below:

Strip Lot	Linear regression equation	R^2	N
1	Y= 0.939x + 6.039	0.991	100
2	Y= 0.952x + 3.230	0.991	100
3	Y= 0.987x + 0.558	0.993	100
Combined	Y= 0.994x – 0.204	0.991	100

Based on the ISO Standard 15197:2003(E), the glucose meter measurements obtained using the OneTouch Verio IQ BGMS as compared to the YSI method for fingersticks and contrived samples were evaluated and results are shown is the following tables:

System accuracy results for glucose concentration <75 mg/dL

Strip Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Combined	45/51 (88.2%)	51/51 (100%)	51/51 (100%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Strip Lot	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Combined	177/249 (71.1%)	236/249 (94.8%)	244/249 (98.0%)	249/249 (100%)

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):

Lay user performance study:

This study was conducted following the ISO Standard 15197 and compared layuser self-test fingerstick measurements to the YSI method. The study was performed in three clinical sites with 276 subjects, 47% female and 52.4% male. The results of this study support the claimed measuring range of 20-600 mg/dL.

System accuracy results for glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
18/31 (58.1%)	31/31 (100%)	31/31 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
159/245 (64.9%)	229/245 (93.5%)	243/245 (99.2%)	244/245 (99.6%)

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

Tester	Linear Regression	R^2	N
Lay user vs. YSI	Y= 0.95x + 5.30	0.99	276

4. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:
For people without diabetes:
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, 2010

N. Instrument Name:

OneTouch® Verio™ IQ Meter

O. System Descriptions:

1. Modes of Operation:

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

   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 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 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 IQ 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 a 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. 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. Altitude Study:

This study was conducted to evaluate the effect of altitude on the OneTouch Verio IQ BGMS. Three (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 at sea level (0 feet) as a control. In addition, testing was performed in a hyperbaric chamber. Each venous blood sample was tested on the OneTouch Verio IQ Blood Glucose monitor and the meter readings obtained were compared to the YSI method; then analyzed as a bias difference. Based on the data, the OneTouch Verio IQ BGMS can be used at altitudes up to 10,000 feet. The glucose values obtained using the OneTouch Verio IQ had biases that were within +/-10 of glucose values obtained at sea level.

2. 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, each test strip lot was tested with three samples, at each of the five glucose levels (30, 65, 240, 450, and 560 mg/dL) Three lots of test strips were tested on 12 meters and the values were compared to the YSI method. The sponsor claimed that hematocrit values between 20% to 60% do not significantly affect the glucose results. The glucose values obtained using the OneTouch Verio IQ were within +/- 15% of the glucose values obtained using the YSI method.

3. Temperature and Relative Humidity Study:

In this study, three test strip lots were tested at 9 combined temperature and relative humidity conditions, including the nominal conditions (22ºC/50% RH) and eight conditions at the limits of the claimed temperature/relative humidity ranges. Temperatures evaluated ranged from 5ºC to 45ºC and relative humidity from 10% to 90%. Each sample tested was also compared to the YSI reference method. The study was conducted over four days, with each day the nominal T/RH condition (22ºC/50% RH) was tested along with two extreme temperature/relative humidity conditions. Three blood samples were adjusted to target glucose concentrations of 65, 240, and 450 mg/dL. At each T/RH condition, two replicates on six meters were obtained for each donor, glucose level and test strip lot (N=108 tests per strip lot).). The results supported the Sponsor's claimed operating temperature from 5^{o}C to 45^{o}C (41^{o}F to 113^{o}F) and relative humidity range from 10% to 90%.

4. EMC - Electromagnetic Compatibility and Electrical Safety verification testing of the OneTouch® Verio™IQ Blood Glucose Monitoring System was performed following the requirements of ISO 15197:2003(E), Section 6. In addition to ISO 15197:2003 (E), verification testing was carried out in accordance with the system-level performance criteria specified in OneTouch® Verio™IQ Product Requirements Document (PRD). All series of testing were performed in accordance with ISO 15197:2003 (E) as applicable to the meter. The following series of testing was performed:

   Protection Against Electric Shock, Protection Against Mechanical Hazards, Electromagnetic Compatibility (Radiated Emissions), Electromagnetic Compatibility and Electrical Safety,Electromagnetic Compatibility (Radiated Radio Frequency Immunity), Electromagnetic Compatibility (Electrostatic Discharge Immunity) Electromagnetic Compatibility (AC Power), Resistance to Heat, Resistance to Moisture and Liquids, Protection Against Liberated Gasses, Explosions, and Implosion, Meter Components, Mechanical Resistance to Shock, Vibration, and Impact (Vibration), Mechanical Resistance to Shock, Vibration, and Impact (Drop Test),Equipment Temperature Exposure Limits, and Equipment Humidity Exposure Limits

   All tests were conducted to meet applicable international standards for safety and reliability of the OneTouch® Verio™IQ Blood Glucose Meter. The software documentation for EMC testing was reviewed and was found to support that the device was developed and is under good software lifecycle processes. A certification is provided by the sponsor.

5. Sample volume study – LifeScan performed a sample volume study to demonstrate that 0.4µL of whole blood is sufficient volume for the LifeScan Verio IQ BGM system. LifeScan performed testing of 0.201µL - 0.469µL sample volumes using three different lots of strips. The blood glucose results for samples collected using sample volumes of at least 0.4µL demonstrated biases within +/- 10% of glucose values obtained with the YSI 2300.

6. Infection control – The device (LifeScan Verio IQ Blood Glucose Meter) is intended for single - patient use. Disinfection studies were performed on the meter and lancet device by an outside commercial testing service to determine the disinfection efficacy of the meter and lancing device to the recommended cleaning and disinfection protocol, and its effectiveness in preventing the spread of bloodborne pathogens, to include hepatitis B virus (HBV). Clorox Germicidal wipes (EPA Reg. No 67619-12) were validated, demonstrating complete inactivation of live virus for use with the meter and lancing device. The sponsor also conducted robustness studies and demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 1,825 cleaning and disinfection cycles to simulate 5 years of use by lay-users. Each robustness cycle consisted of one pre-clean wipe and one disinfecting wipe.

7. Readability: A Flesch-Kincaid analysis was performed and determined that the overall reading grade level for the OneTouch Verio test strip insert and control solution insert were 5.9 and 7.7, respectively. The Flesch-Kincaid reading level assessment for the OneTouch VerioIQ Owners' Booklet is 8.4.

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.