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

A. 510(k) Number:

k131363

B. Purpose for Submission:

Modifications to existing device. Specifically, the modifications include the following: Change in shape and size, location of buttons, removal of a test strip port connector backlight, decrease in the number of control and blood glucose results stored in the meter memory to 500, minor software changes, larger and greater resolution LCD screen, change from rechargeable battery to two standard non-rechargeable AAA alkaline batteries, change from mini to Micro USB data port, change in low and high pattern alert ranges.

C. Measurand:

Capillary whole blood glucose from the fingertip

D. Type of Test:

Quantitative, amperometric detection, Flavin adenine dinucleotide-Glucose dehydrogenase (GDH-FAD)

E. Applicant:

LifeScan Europe, a division of Cilag GmbH International

F. Proprietary and Established Names:

OneTouch® Verio® 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
   LFR- Glucose dehydrogenase, glucose

4. Panel:

   Clinical Chemistry (75)

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 fingertip. The system is intended to be used by a single patient and should not be shared.

   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 is not to be used for the diagnosis of or screening for diabetes or for neonatal use.

   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 drawn from the fingertips.

3. Special conditions for use statement(s):
   For over the counter use
   For single-patient use only
   Not for neonatal use
   Not for screening for or diagnosis of diabetes
   Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.

4. Special instrument requirements:
   OneTouch® Verio Meter

I. Device Description:

The OneTouch® Verio® Blood Glucose Monitoring System consist of the OneTouch®

Verio® Blood Glucose Meter, OneTouch® Verio® Test Strips (available separately), OneTouch® Verio® Level 3 and Level 4 Control Solutions (available separately, previously cleared in k093745). The OneTouch® Delica® Lancing Device and Sterile lancets, carrying case, owners booklet and get started guide are accessories to the OneTouch® Verio® Blood Glucose Monitoring System and are provided as part of the system kit. The OneTouch® Verio® Blood Glucose Monitoring System measures the glucose content of a blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement. The OneTouch Verio meter has a high/low pattern alert feature that was originally cleared in k110637 to detect patterns of high and/or low glucose readings over a set period of time. The low pattern alert in the candidate device has been modified from 50-90mg/dL to 60-110mg/dL and the high pattern alert has been modified from 100-160mg/dL to 120-300mg/dL.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   OneTouch® Verio® IQ Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
   k110637

3. Comparison with predicate:

Similarities		
Item	Candidate Device OneTouch® Verio® Blood Glucose Monitoring System	Predicate Device OneTouch® Verio® IQ Blood Glucose Monitoring System (k110637)
Indications for Use	The OneTouch® Verio® Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip as an aid to monitor the effectiveness of diabetes control in people with diabetes. The system is intended to be used by a single patient and should not be used for testing multiple patients. This system is not to be used for the diagnosis of or screening of diabetes or for neonatal use.	Same
Operating principal	Electrochemical reaction with Glucose dehydrogenase-flavin adenine dinucleotide (GDH-FAD)	Same
Detection	Amperometry	Same

Similarities		
Item	Candidate Device OneTouch® Verio® Blood Glucose Monitoring System	Predicate Device OneTouch® Verio® IQ Blood Glucose Monitoring System (k110637)
Sample type	Fresh capillary whole blood	Same
Averages	7,14 30, and 90 day averages	Same
Measuring time	5 seconds	Same
Test range	20-600mg/dL	Same
Coding	No Coding	Same
Auditory indicator	None	Same

Differences		
Item	Candidate Device OneTouch® Verio® Blood Glucose Monitoring System	Predicate Device OneTouch® Verio® IQ Blood Glucose Monitoring System (k110637)
Sample site	Fingertip	Fingertip, forearm, and palm
Memory	500 control and blood glucose results	750 control and blood glucose results
Power source	2 x 1.5 V (AAA)	3.7 V Lithium Ion rechargeable battery
Strip Port Connector (SPC)	Common Gemini SPC	OneTouch® Verio™ SPC
User Interface Screen	Low Pattern Alert Range (60-110mg/dL) High Pattern Alert Range (120-300mg/dL)	Low Pattern Alert Range (50-90mg/dL) High Pattern Alert Range (100-160mg/dL)
	Addition of Progress notes, range indicator and treat low glucose results messaging	Hi-Lo Pattern alert to detect patterns of high and/ or low glucose over a set period of time
Data Download	Micro USB data port	Mini USB data port
Size	0.99 x 2.04 x 3.15 inches	3.46 x 1.85 x 0.47 inches
Weight	Approx 3 ounces	Approx 1.7 ounces
Meal Flags	None	Pre and Post
LCD	Color display (320 x 640 pixels) Dimensions (37 x 49mm)	Color display (176 x 220 pixels) Dimensions (30 x 40mm)

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

- ISO 15197:2003(E)- In vitro diagnostic test systems- Requirements for In Vitro Whole Blood glucose
- CLSI-EP6-A- Evaluation of the Linearity of Quantitative Measurement Procedures:

A Statistical Approach; Approved Guideline
- CLSI EP7-A2- Interference Testing in Clinical Chemistry; Approved Guideline

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 enzymatic 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 the current generated from the redox reaction as the measurable response.

M. Performance Characteristics (if/when applicable):

New performance data was not necessary as the modifications made to the meter would not affect device performance. Therefore, device performance is as established in k110637.

1. Analytical performance:

a. Precision/Reproducibility:

Precision was established in k110637.

b. Linearity/assay reportable range:

Linearity was established in k110637. The claimed range of measurement for this glucose device is 20-600mg/dL.

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

Traceability:
The OneTouch Verio Blood Glucose Monitoring System is traceable to the NIST SRM 917b reference material. The method comparison study was performed using the candidate device and YSI as the reference method.

Test strip stability:
Stability was previously established in k120708.
Control solution stability:
Control solution stability was previously in k120708.

Value Assignment:
Value assignment for the controls was previously established in k120708.

d. Detection limit:
The measuring range of the OneTouch Verio Blood Glucose Monitoring system is 20-600mg/dl based on linearity studies established in k110637.

e. Analytical specificity:

Analytical specificity established in k110637.

The sponsor has the following limitations in their labeling:

"Tolazamide at concentrations greater than 10.8 mg/dL may cause falsely low results."

"Uric acid at concentrations greater than 8 mg/dL may cause falsely low results."

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

f. Assay cut-off:
Not Applicable.

2. Comparison studies:

a. Method comparison with predicate device:
System Accuracy Study
The sponsor performed a system accuracy evaluation comparing the OneTouch Verio BGMS to YSI 2300 (reference method). The study was performed at three clinical sites. Capillary fingerstick samples collected from 100 subjects over 25 days with glucose concentrations ranging from 31.6 to 492.5mg/dL were analyzed with the candidate device and with YSI. Two of the samples tested were adjusted <50mg/dL and four samples were adjusted >400mg/dL glucose concentration ranges. The OneTouch Verio was tested in duplicate with each of three different strip lots providing a total of 6 meter results per participant. The results for a singlet set of data relative to the reference method are summarized in the tables below:

For capillary blood glucose concentrations <75mg/dL

Test Strip Lot	Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
1	9/23 (39.1%)	22/23 (95.7%)	23/23 (100%)
2	14/29 (60.9%)	21/23 (91.3%)	23/23 (100%)
3	12/23 (52.2%)	19/23 (82.6%)	23/23 (100%)
Combined	35/69 (50.7%)	62.69 (89.9%)	69/69 (100%)

For capillary blood glucose concentrations ≥75mg/dL

Test Strip Lot	Within ±5%	Within ±10%	Within ±15%	Within ±20%
1	47/77 (61.0%)	67/77 (87.0%)	76/77 (98.7%)	77/77 (100%)
2	46/77 (59.7%)	67/77 (87.0%)	74/77 (96.1%)	77/77 (100%)
3	51/77	72/77	76/77	77/77

	(66.2%)	(93.5%)	(98.7%)	(100%)
Combined	144/231 (62.3%)	206/231 (89.2%)	226/231 (97.8%)	231/231 (100%)

Linear Regression

Test Strip Lot	N	Intercept mg/dL (with 95% CI)	Slope (with 95% CI)	r^2
1	100	5.00 (1.31-8.68)	0.99 (0.98-1.01)	0.99
2	100	5.53 (1.78-9.28)	0.98 (0.96-1.00)	0.99
3	100	4.90 (1.54-8.27)	0.99 (0.97-1.00)	0.99

b. Matrix comparison:
Not applicable. Capillary whole blood is the only indicated 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 Study/User Performance Study:
The Lay user study was conducted following the ISO Standard 15197. To assess the performance of the OneTouch Verio BGMS in the hands of the intended users, the sponsor performed a study with 189 (53.4% female and 46.6% male) untrained lay user participants. The study was performed at four clinical sites and was conducted in 2 site visits. Each subject was asked to review the instructions for use and meter and perform testing on a fingertip. Each subject produced a blood drop large enough for two meter tests, one on an OneTouch Verio meter and Verio Test strip and the other for the healthcare professional to immediately perform a blood glucose test on another OneTouch Verio meter and Verio test strip from the same test strip lot. The HCP also collected blood for two YSI 2300 tests and for hematocrit testing. The range of glucose values for the samples as measured by the reference method was 31.8 to 495.3mg/dL. Results are summarized below:

For glucose concentrations <75 mg/dL

within ±5 mg/dL	**within ±10 mg/dL**	**within ±15 mg/dL**
7/20 (35%)	18/20 (90%)	19/20 (95%)

For glucose concentrations ≥75 mg/dL

within ±5 %	**within ±10 %**	**within ±15 %**	**within ±20 %**
95/169 (56.2%)	144/169 (85.2%)	161/169 (95.3%)	167/169 (98.8%)

Linear Regression Analysis:

Tester	N	Linear regression	r^2
Subject vs YSI	189	y=0.98x+7.03	0.99

4. Clinical cut-off**:**
   Not Applicable.

5. Expected values/Reference range:
   The expected blood glucose levels for non-pregnant people without diabetes[1]:

Time of day	Range, mg/dL
Fasting	Less than 100 mg/dL
2 hours after meals	Less than 140 mg/dL

[1]American Diabetes Association, Position Statement, Diagnosis and Classification of Diabetes Mellitus, Diabetes Care 35:S4-S10, 2012.

N. Instrument Name:

OneTouch® Verio® Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:
   Each test strip is single use and must be replaced with a new strip for additional readings. The minimal sample volume is 0.4µL.

   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 ___

   The sponsor states there are no unresolved anomalies for the OneTouch Verio software release OX0102_001.

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 device 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:

   The meter is a non-coding device; therefore no coding is required by the user.

6. Quality Control:

   The sponsor manufactures two levels of glucose control solutions (OneTouch Verio Level 3 Control Solution and OneTouch Verio Level 4 Control Solution) that can be run with this device but are available separately from the system. The meter has an algorithm to automatically recognize when a control solution is being analyzed. The words "Control Solution" appears on screen and the meter automatically marks the result as a control solution test. Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the test strip vial label. If the control values fall outside these ranges, the user is referred to the user manual and customer support for more information.

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

1. **Hematocrit Study:** Established in k110637.

2. **Sample Volume Study:** Established in k110637.

3. **Sample Identification (Blood vs. Control solution):** The sponsor performed a sample type identification study. Seven OneTouch Verio test strip lots using blood and control solution on OneTouch Verio meters were used during performance evaluation testing. The results demonstrate that the OneTouch Verio BGMS was able to correctly distinguish between blood and control solution.

4. **Altitude Study:** Established in k110637.

5. **Temperature and Humidity Studies:** Established in k110637.

6. **Infection Control Studies:** The OneTouch Verio Blood Glucose Meter is intended for single-patient use. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial laboratory testing

services to demonstrate complete inactivation of hepatitis B virus (HBV) with Clorox Germicidal Wipes (EPA Reg. No. 67619-12). The sponsor also conducted robustness studies and demonstrated that there was no change in performance or in the external materials of the meter after 2879 cleaning and 412 disinfection cycles to simulate 3 years of use by the lay-user. Each robustness cycle consisted of one pre-clean wipe and one disinfecting wipe. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. **EMC testing:** The sponsor states that they followed requirements of ISO 15197:2003(E) and associated normative standards. Electromagnetic compatibility and Electrical Safety verification testing of the OneTouch Verio Blood Glucose Monitoring System was performed following the requirements of ISO 15197:2003(E) by CSA International and letters of attestation dated June 12th and 14th 2012 were submitted stating that the device met all of the requirements of the following standards:

   IEC 61010-1
   IEC 61010-2-101:2002
   IEC 61010-1:2001
   IEC 61010-2-101:04
   IEC 61326-1:2005 Annex A
   IEC 61326-2-6: 2007
   IEC 61000-4-2:2008

8. **Readability Assessment:** A Flesch-Kinkaid reading level assessment was conducted of the OneTouch Verio Owners Booklet were assessed, giving a readability grade level of 6.1

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.