

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

A. 510(k) Number:

k120708

B. Purpose for Submission:

New Device

C. Measurand:

Capillary Whole Blood Glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose dehydrogenase (FAD)

E. Applicant:

Cilag Gmbh International

F. Proprietary and Established Names:

OneTouch Verio Sync Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LFR – Glucose dehydrogenase, glucose	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
NBW – system, test, blood glucose, over the counter	Class II	21 CFR § 862.1345	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The OneTouch Verio Sync Blood Glucose Monitoring System (BGMS) 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 person and should not be shared.

The OneTouch Verio Sync BGMS 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 Sync BGMS should not be used for the diagnosis of or screening of diabetes or for neonatal use.

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

3. Special conditions for use statement(s):

For over-the-counter use.

Not for neonatal use, nor for screening for or diagnosis of diabetes mellitus.

Not for use on critically ill patients, patients in shock, dehydrated patients, hypotensive patients or hyper-osmolar patients.

For single patient use only and should not be shared.

4. Special instrument requirements:

OneTouch Verio Sync Blood Glucose Meter

I. Device Description:

The OneTouch® Verio™ Sync Blood Glucose Monitoring System consists of the following components:

- OneTouch Verio Sync Meter
- OneTouch Verio Level 3 Control Solution (available separately)
- OneTouch Verio Level 4 Control Solution (available separately)

- OneTouch Verio Test Strips (available separately)
- OneTouch Delica Lancing Device
- OneTouch Delica Sterile Lancets
- Carrying Case
- AC Adaptor (wall charger)
- USB Cable
- OneTouch® Verio Sync Product Labeling

Accessories available separately for the OneTouch® Verio Sync Blood Glucose Monitoring System include the OneTouch Reveal Diabetes Management Application (cleared under k120558) and the OneTouch® Diabetes Management Software (DMS – cleared under k 984527).

J. Substantial Equivalence Information:

1. Predicate device name(s):

OneTouch Verio Blood Glucose Monitoring System

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

k093745

3. Comparison with predicate:

Similarities		
Item	Candidate Device	Predicate (k093745)
Indications for Use	Same	For the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples.
Operating principle / methodology	Same	Electrochemical reaction with GDH-FAD Glucose Dehydrogenase
Minimum sample volume	Same	0.4 µL
Test time	Same	5 seconds
Measuring range	Same	20 – 600 mg/dL
Calibration	Same	No coding required
Hematocrit range	Same	20 – 60%
Operating humidity range	Same	10 – 90% non-condensing
Units	Same	mg/dL, not user

Similarities		
Item	Candidate Device	Predicate (k093745)
		changeable

Differences		
Item	Candidate Device	Predicate (k093745)
Sampling sites	Fingertip only	Fingertip, forearm, and palm
Physical dimensions	3.9 x 1.6 x 0.5 inches, 1.7 oz.	2.9 x 2.2 x 0.8 inches, 1.9 oz
Operating Temperature Range	50 – 111° F 10 – 44 ° C	43 – 111° F 6 – 44 ° C
Buttons	1 button: Turns meter off and on, changes the illumination level and toggles device between bluetooth and airplane mode	4 buttons: Up/down/OK/Back on face of the device
Control solutions and target levels	Level 3: 120 mg/dL	Mid: 120 mg/dL
	Level 4: 350 mg/dL	High: 350 mg/dL
Result averaging	None. Averages are calculated only by the OneTouch Reveal Diabetes Management Application	7, 14, and 30 day averages
Date / time setting	The date and time are set by the OneTouch Reveal Diabetes Management Application.	Date and time are user set
Wireless data transmission capability	Bluetooth wireless transmission to the paired Apple partner device.	None

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

CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach.

CLSI EP07-A: Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition.

ISO 15197:2003 In Vitro Diagnostic Test Systems- Requirements For In Vitro Whole Blood Glucose

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:*

Repeatability

Venous blood from one donor with nominal hematocrit (37 - 45%) collected with lithium heparin anticoagulant, was adjusted with glucose to five glucose levels (30-50, 51-110, 111-150, 151-250, 251-400) across the claimed range and tested on three lots of production strips on 30 meters (10 meters per test strip lot). Ten replicates were tested per meter, test strip lot and glucose concentration. The testing for each group of 10 meters was executed by one operator over one day. Results are summarized below:

Test Strip Lot 1

Glucose conc. (mg/dL)	30-50	51-110	111-150	151-250	251-400
n	100	100	100	100	100
Mean (mg/dL)	44.51	102.42	133.41	203.8	354.04
Std Dev (mg/dL)	0.82	1.98	2.49	4.18	7.56
CV (%)	1.84	1.93	1.87	2.05	2.14

Test Strip Lot 2

Glucose conc. (mg/dL)	30-50	51-110	111-150	151-250	251-400
n	100	100	100	100	100
Mean (mg/dL)	35.92	104.48	132.17	201.68	333.16
Std Dev (mg/dL)	1.02	3.17	3.68	4.5	10.12
CV (%)	2.84	3.03	2.78	2.23	3.04

Test Strip Lot 3

Glucose conc.(mg/dL)	30-50	51-110	111-150	151-250	251-400
n	100	100	100	100	100
Mean (mg/dL)	34.99	97.49	136.54	193.8	349.54
Std Dev (mg/dL)	0.75	2.37	2.62	5.17	9.33
CV (%)	2.14	2.43	1.92	2.67	2.67

Intermediate Precision

In this study, three test strip lots were tested with control solutions at three different concentrations. The test was performed with 30 meters over 10 days, and 20 replicates per day.

Test Strip Lot 1

Glucose concentration range (mg/dL)	Control Level 1	Control Level 2	Control Level 3
	30-50	96-144	280-420
Mean (mg/dL)	37.76	116.51	335.27
n	200	200	200
Std Dev (mg/dL)	0.82	1.74	5.61
CV (%)	2.17	1.49	1.67

Test Strip Lot 2

Glucose concentration range (mg/dL)	Control Level 1	Control Level 2	Control Level 3
	30-50	96-144	280-420
Mean (mg/dL)	38.65	116.91	335.75
n	200	200	200
Std Dev (mg/dL)	0.88	2.10	6.35
CV (%)	2.28	1.80	1.89

Test Strip Lot 3

Glucose concentration range (mg/dL)	Control Level 1	Control Level 2	Control Level 3
	30-50	96-144	280-420
Mean (mg/dL)	39.49	118.75	336.70
n	200	200	200
Std Dev (mg/dL)	0.93	2.07	6.73
CV (%)	2.36	1.74	2.00

b. *Linearity/assay reportable range:*

In this study, venous blood from nine donors (with nominal hematocrits of 37-45%) was adjusted to eight target glucose levels (20, 100, 200, 300, 400, 500, 600 and 700 mg/dL) and tested with 3 OneTouch Verio Test Strip lots on eight OneTouch Verio Sync Blood Glucose Meters. Each sample was also assayed with the YSI reference method. Note: The target glucose of 700 mg/dL exceeds that of the claimed OneTouch Verio Sync Blood Glucose Monitoring System glucose concentration range which is 20 - 600 mg/dL. The meters were modified to display a glucose result greater than 600 mg/dL. Linear regression of the data produced the following:

Strip Lot	Intercept (with 95% CI)	Slope (with 95% CI)	r ²
1	2.8 (2.1 – 3.5)	0.969 (0.965 – 0.972)	0.996
2	4.6 (3.9 – 5.3)	0.958 (0.954 – 0.961)	0.996
3	5.2 (4.4 – 5.9)	0.973 (0.969 – 0.976)	0.996

The results of the study support the sponsor’s claimed glucose measurement range of 20 – 600 mg/dL.

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

Traceability:

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

Test Strip Stability

Closed vial (shelf life) stability was assessed in real-time studies. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the claimed shelf life of 22 months when stored at 41 - 86° F (5 - 30° C).

Opened vial (in-use) stability was assessed in real-time studies. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the open vial stability of six months when stored at 41 - 86° F (5 - 30° C).

Control Solution Stability:

Control shelf-life stability (closed vial) was assessed in real-time studies. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the claimed shelf life of 24 months when stored at 41 - 86° F (5 - 30° C).

Control in-use stability (open vial) was assessed in real-time studies. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the open vial stability of six months when stored at 41 - 86° F (5 - 30° C).

d. Detection limit:

The measuring range of the OneTouch Verio Sync Blood Glucose Monitoring System is 20 – 600 mg/dL. This range was validated by the linearity study (M.1.b).

e. Analytical specificity:

The sponsor performed interference studies in accordance with CLSI EP7-A. Testing was performed in parallel (control samples vs. test samples) to minimize the effects of glucose metabolism.

Venous blood was drawn into Lithium heparin anticoagulant tubes from healthy volunteers. The glucose levels tested were 65 and 240 mg/dL. Samples were allowed to glycolyze or were spiked, as needed, to achieve the 65 and 240 mg/dL glucose levels. A low and high concentration of each potential interferent was then tested at each glucose level. The following substances were found not to interfere at the concentrations listed:

<u>Endogenous Substances</u>	No interference up to (mg/dL in plasma):
Ascorbic Acid	10.2
Bilirubin	32.5
Cholesterol	837
Creatinine	8.5
Glutathione	12.8
Triglycerides	3331
Urea	424
Uric Acid	8
Lactose	35.8
Galactose	105
Maltose	349
<u>Exogenous Substances</u>	No interference up to (mg/dL in plasma):
Acetaminophen	8
Dopamine	0.18
Ephedrine	0.35
Gentisic Acid	1.8
Ibuprofen	86.0
Levo dopa	1.7

Methyl dopa	2.54
Salicylate	103
Tolazamide	10.8
Tolbutamide	110

The sponsor has the following limitations in their labeling:

Tolazamide	Concentrations greater than 10.8mg/dL may cause falsely low results
Uric Acid	Concentrations greater than 8mg/dL may cause falsely low results

f. Assay cut-off:

Not Applicable.

2. Comparison studies:

a. Method comparison with predicate device:

System Accuracy Study

To assess system accuracy, results from the OneTouch Verio Sync Blood Glucose Monitoring System were compared to a reference method (YSI 2300). Capillary fingerstick samples from 100 participants with glucose concentrations ranging from 40 - 434 mg/dL were analyzed with the candidate device and with YSI. Three samples were collected from each fingerstick. The first was used for the Verio Sync measurement, the second for the YSI measurement, and the third for a hematocrit measurement. Two participant samples were allowed to glycolyze to obtain a glucose concentration < 50 mg/dL and three participant samples were spiked to obtain a glucose concentration > 400 mg/dL. The results relative to the reference method are summarized in the tables below:

Concentrations < 75 mg/dL

Strip Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	15/19 (79%)	18/19 (95%)	19/19 (100%)
2	14/19 (74%)	18/19 (95%)	19/19 (100%)
3	11/19 (58%)	19/19 (100%)	19/19 (100%)
All	40/57 (70%)	55/57 (96%)	57/57 (100%)

Concentrations ≥ 75 mg/dL

Strip Lot	Within \pm 5%	Within \pm 10%	Within \pm 15%	Within \pm 20%
1	60/81 (74%)	78/81 (96%)	81/81 (100%)	81/81 (100%)
2	59/81 (73%)	79/81 (98%)	81/81 (100%)	81/81 (100%)
3	55/81 (68%)	78/81 (96%)	80/81 (99%)	81/81 (100%)
All	174/243 (72%)	235/243 (97%)	242/243 (99.59%)	243/243 (100%)

Linear Regressions

Strip Lot	n	Intercept (with 95% CI)	Slope (with 95% CI)	r ²
1	100	1.16 (-2.11 – 4.43)	1.00 (0.99 – 1.02)	0.993
2	100	1.96 (-1.31 – 5.23)	0.99 (0.97 – 1.01)	0.993
3	100	4.7 (0.77 – 8.66)	0.99 (0.97 – 1.01)	0.990

b. *Matrix comparison:*

Not Applicable. Only fresh capillary whole blood samples from the fingertip may be used.

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 Verio Sync Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a study with 273 untrained lay user participants. Each participant collected and analyzed their own fingerstick sample. A second fingerstick sample was then collected and analyzed on the YSI reference method. The study was performed at three clinical sites and the gender breakdown was 53% male and 47% female. Three lots of test strips were used and single measurements collected by the users were compared to the reference method. None of the samples were altered before analysis. The range of glucose values for the samples as measured by the reference method was 49 - 506 mg/dL. Results are summarized below:

Concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
5/23 (22%)	15/23 (65%)	22/23 (96%)

Concentrations ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
141/250 (56%)	219/250 (88%)	242/250 (97%)	248/250 (99%)

Linear Regression

n	Intercept (with 95% CI)	Slope (with 95% CI)	r ²
273	8.84 (5.64 – 12.0)	0.96 (0.94 – 0.98)	0.98

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

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

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

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

N. Instrument Name:

OneTouch Verio Sync 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 minimum sample volume is 0.4 uL.

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes No

Does the applicant's device transmit data to a computer, webserver, or mobile device

using wireless transmission?

Yes No

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes 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 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:

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

6. Quality Control:

Glucose control solutions at two different concentrations are supplied with the device. The meter has an algorithm to automatically recognize when a control solution is being analyzed. *Control solution test results are stored in the meter, but are not sent to the Apple device.* 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. 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. Hematocrit Study

Three OneTouch Verio Test Strip lots were tested on 12 Verio Sync meters at each of the following five hematocrit levels: 19, 30, 44, 50 and 61%. At each hematocrit level, each lot was tested with three donor venous blood samples at each of five glucose levels: 30, 66, 118, 233, 455, and 563 mg/dL. A single replicate on each of the 12 meters was obtained for each combination of test

strip/glucose level/hematocrit and donor. This resulted in n = 180 data points per strip lot at each hematocrit level (5 glucose levels x 3 donors x 12 meters). Samples were also tested by the YSI reference method. The results demonstrated that the OneTouch Verio Blood Glucose Monitoring System produces accurate results over the claimed hematocrit range of 20 – 60%.

2. Sample Volume Study

The sponsor performed a sample volume study to support the claimed minimum sample volume requirement for the OneTouch Verio Sync Blood Glucose Monitoring System (0.4 μ L) using blood samples at two glucose concentrations (65 and 450 mg/dL). The system displays an error code when insufficient sample is detected. Results support the claimed sample volume of 0.4 μ L.

3. Altitude Study

In this study, three (3) test strip lots were tested on sixteen (16) Verio Sync meters using venous blood from three (3) donors (with nominal hematocrit (37-45%)) and adjusting them to 70, 240 and 450 mg/dL. The samples were tested at three altitude levels (3000, 6000 and 10,000 feet), and at sea level (0 feet) as a control. This resulted in n = 288 data points per strip lot at each altitude level (3 donors x 3 glucose levels x 16 meters x 2 replicates). Each blood sample was also tested by the YSI reference method. The bias relative to the reference method was acceptable to support the claim that altitudes up to 10,000 feet do not significantly affect the glucose results.

4. Temperature and Humidity Studies

The sponsor performed temperature and humidity studies using venous blood samples at target glucose concentrations of 65, 240 and 450 mg/dL to evaluate temperatures ranging from 50 – 111°F (10 – 44°C) and relative humidity from 10 – 90 %. Combinations of the claimed temperature and humidity operating conditions were evaluated by comparing meter results to the YSI reference method. The bias relative to the reference method was acceptable to support the claim that temperatures from 50 – 111° F (10 – 44°C) and relative humidity from 10 – 90% do not significantly affect the glucose results.

5. Infection Control Studies

This device is intended for single patient use.

Clorox Germicidal wipes (EPA registration #67619-2) were validated demonstrating complete inactivation of live virus using materials from the meter and lancing device. The sponsor also demonstrated (separately for each product) that there was no change in performance or in the external materials after 310 cleaning and disinfection cycles for the meter and lancing device (one cycle

includes one cleaning wipe plus one disinfecting wipe). This simulated 3 years of use for the meter and lancet device. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. EMC testing

Electromagnetic Compatibility (EMC) Testing was evaluated and certified by Elliott Laboratories, Inc. and a letter of attestation dated September 6, 2011 was submitted stating that the device met all of the requirements of the following standards:

IEC 60068-2-64:1993

IEC 61010-1 :2001

IEC 61326-1 :2005, IEC 61326-2-6:2005 and IEC 61010-2-101

7. Readability Assessment

The sponsor provided a readability assessment of the Owner's Booklet and Test Strip Insert. The Flesch-Kincaid analysis produced a grade level of 8.3 and 7.9 respectively.

8. Customer service is available 7 days a week from 8:00 am to 10:00 pm EST by calling 1-888-567-3003. The labeling instructs users to contact their healthcare professional if they cannot reach customer service.

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.