510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k113135

B. Purpose for Submission:

Alternative blood glucose test strips for use with LifeScan OneTouch Ultra, Ultra2, UltraSmart and UltraMini blood glucose meters purchased before October 2012 with test strip calibration code 49.

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative Amperometric assay (Glucose Oxidase)

E. Applicant:

UniStrip Technologies, LLC

F. Proprietary and Established Names:

UniStrip 1

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

   CGA, Glucose Oxidase, Glucose

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:
   The Unistrip1 Test Strips are used with the OneTouch® Ultra®, OneTouch®Ultra2®, OneTouch® UltraMini® and One-Touch® UltraSmart® meters purchased before October 2012, set at calibration code 49, for measuring glucose (sugar) in whole capillary blood. The Unistrip1 is meant for self-testing of blood glucose as an aid to monitor the effectiveness of diabetes control.

   They are for single patient use only and should not be shared.

   They are used to quantitatively measure glucose in fresh capillary whole blood samples taken from the finger, palm, or forearm.

   Testing is done outside the body (in vitro diagnostic use).

   They are indicated for use by people with diabetes in their home as an aid to monitor the effectiveness of diabetes control.

   Not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

   UniStrip1 Test Strips allow alternate site testing (AST) from the fingertip, palm and/or the forearm. (Use of palm AST is not to be done with OneTouch®Ultra® meter). Alternative site testing should only be done during steady-state times (when glucose is not changing rapidly).

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
   - Alternative site testing (AST) testing should only be done during steady-state times (when glucose is not changing rapidly).
   - AST should not be used to calibrate continuous glucose monitors (CGMs).

- AST should not be used for insulin dose calculations.

4. Special instrument requirements:

   LifeScan OneTouch Ultra, Ultra2, UltraSmart and UltraMini blood glucose meters purchased before October 2012 with test strip calibration code 49.

I. Device Description:

The UniStrip1 Test Strips are used with the OneTouch Ultra, OneTouch Ultra2, OneTouch UltraMini and OneTouch UltraSmart glucose monitoring meters purchased before October 2012 for qualitatively measuring glucose in fresh capillary whole blood. UniStrip1 Test Strips are used in fingertip, forearm, and palm testing. Each test strip contains glucose oxidase (Aspergillus niger), potassium ferricyanide, buffer and other non-reactive ingredients. UniStrip test strips are only for use with calibration code 49.

The UniStrip test strip package insert instructs the user to check their device using the low and high Prodigy® Control Solutions. Expected control ranges for the low (25-70 mg/dL) and high (200-300 mg/dL) Prodigy Control Solutions are shown on the test strip vial.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   One Touch Test Strips (OneTouch Blood Glucose Test System)

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

   k923544

3. Comparison with predicate:

Comparison Table		
Item	Device (k113135)	Predicate (k923544)
Indications for Use	Quantitative determination of glucose concentrations in blood as an aid in monitoring effectiveness of diabetes control.	Same
Alternative Site Testing	Fingertip, forearm, and palm	Fingertip and earlobe
Detection method	Amperometry	colorimetric reflectance
Enzyme	Glucose Oxidase (Aspergillus niger)	same

Comparison Table		
Item	Device (k113135)	Predicate (k923544)
Sample volume	1.0 uL	Not specified
Reaction time	5 seconds	45 seconds
Measurement range	20-600 mg/dL	0-600 mg/dL
Hematocrit range	30 - 55%	25 – 60%
Storage conditions	Store at < 30°C until expiration date.	Store at < 30°C until expiration date. Do not refrigerate.

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. ISO 14971:2007. Medical devices-Application of risk management to medical devices.
3. CLSI EP7-A2. Interference Testing in Clinical Chemistry; Approved Guideline (2005).
4. CLSI EP5-A2. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline (2004).
5. ISO 13640:2002. Stability Testing of *In Vitro* Diagnostic Reagents. (*In Vitro* Diagnostics).
6. CLSI EP6-A. Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003).
7. ISO 5725-1. Accuracy (trueness and precision) of measurement methods and results - Part 1 - General Principles and Definitions.

L. Test Principle:

Glucose in the blood sample mixes with glucose oxidase on the UniStrip1 test strip and a small electrical current is measured by the meter(s) and displayed as your blood glucose results. The strength of this current changes with the amounts of glucose in the blood sample.

M. Performance Characteristics (if/when applicable):

The sponsor states that the following performance evaluation provided for the UniStrip test strips was obtained using the 4 claimed meters (LifeScan OneTouch Ultra, OneTouch Ultra 2, One Touch UltraSmart and OneTouch UltraMini) purchased before October 2012. The sponsor states that UniStrip test strip calibration code 49 was used in each of the performance evaluations.

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

Within-run precision was performed in one day using five blood glucose concentrations. Each sample was tested using calibration code 49 with the UniStrip test strips and the OneTouch®Ultra, OneTouch®Ultra2®, OneTouch UltraMini® and OneTouch® UltraSmart® glucose meters. Three UniStrip test lots were used with each blood glucose meter. Five different meters for each model type above were each used to test each sample in singlicate with all three test strip lots. This resulted in a total of n=25 for each glucose meter model and test strip lot combination for each glucose concentration. The results are summarized below.

One Touch Ultra

Lot 1	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	47	87	127	213	318
SD (mg/dL)	2.6	2.4	4.8	7.4	11.2
%CV	5.5	2.8	3.8	3.5	3.5
Lot 2	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	49	87	125	213	316
SD (mg/dL)	2.3	3.1	3.8	6.3	10.9
%CV	4.7	3.5	3.0	3.0	3.4
Lot 3	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	48	88	126	212	319
SD (mg/dL)	2.1	3.5	5.2	6.2	9.6
%CV	4.4	4.0	4.2	2.9	3.0

One Touch Ultra2

Lot 1	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	48	87	124	213	316
SD (mg/dL)	2.8	2.6	4.8	6.3	11.9
%CV	5.8	3.0	3.9	3.0	3.8
Lot 2	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	48	88	127	214	320
SD (mg/dL)	2.5	3.1	4.4	6.0	11.4
%CV	5.2	3.5	3.5	2.8	3.6
Lot 3	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	48	89	125	210	320
SD	2.8	3.0	4.5	6.4	11.9

(mg/dL)					
%CV	5.8	3.4	3.6	3.1	3.7

One Touch UltraMini

Lot 1	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	47	87	125	212	317
SD (mg/dL)	2.4	2.5	4.2	6.9	9.6
%CV	5.1	2.9	3.3	3.3	3.0
Lot 2	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	47	88	125	212	321
SD (mg/dL)	2.7	3.0	4.6	5.9	10.0
%CV	5.7	3.4	3.7	2.8	3.1
Lot 3	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	49	88	125	211	315
SD (mg/dL)	2.9	2.8	5.1	6.4	11.3
%CV	5.9	3.2	4.1	3.1	3.6

One Touch UltraSmart

Lot 1	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	47	89	126	213	318
SD (mg/dL)	2.6	3.1	4.4	6.5	11.7
%CV	5.5	3.4	3.4	3.1	3.7
Lot 2	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	48	88	128	213	318
SD (mg/dL)	2.5	2.9	4.4	6.4	11.6
%CV	5.2	3.2	3.5	3.0	3.6
Lot 3	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	49	88	126	214	320
SD (mg/dL)	2.4	3.0	4.8	7.0	10.5
%CV	4.9	3.5	3.8	3.3	3.3

Between-run precision was performed over ten days using three blood glucose control

concentrations. Each sample was tested using calibration code 49 with the UniStrip test strips and the OneTouch®Ultra, OneTouch®Ultra2®, OneTouch UltraMini®, and OneTouch® UltraSmart® glucose meters. Three UniStrip test lots were used with each blood glucose meter. Five different meters for each model type above were each used to test each sample in singlicate with all three test strip lots. This resulted in n=5 for each glucose meter model and test strip lot combination each day for each glucose concentration tested over ten days for a total of n=50. Results are summarized below.

One Touch Ultra

Lot 1	Level 1	Level 2	Level 3
Mean (mg/dL)	47	93	291
SD (mg/dL)	3.4	3.2	9.3
%CV	7.2	3.5	3.2
Lot 2	Level 1	Level 2	Level 3
Mean (mg/dL)	48	93	288
SD (mg/dL)	3.4	3.1	9.5
%CV	7.1	3.4	3.3
Lot 3	Level 1	Level 2	Level 3
Mean (mg/dL)	48	94	289
SD (mg/dL)	3.2	2.9	10.3
%CV	6.7	3.1	3.6

One Touch Ultra2

Lot 1	Level 1	Level 2	Level 3
Mean (mg/dL)	48	94	291
SD (mg/dL)	3.5	3.5	11.2
%CV	7.3	3.8	3.8
Lot 2	Level 1	Level 2	Level 3
Mean (mg/dL)	48	93	290
SD (mg/dL)	3.5	3.5	9.4
%CV	7.3	3.8	3.2
Lot 3	Level 1	Level 2	Level 3
Mean	48	93	289

(mg/dL)			
SD (mg/dL)	3.4	3.3	9.7
%CV	7.1	3.6	3.4

One Touch UltraMini

Lot 1	Level 1	Level 2	Level 3
Mean (mg/dL)	48	93	289
SD (mg/dL)	3.6	3.4	8.8
%CV	7.5	3.7	3.1
Lot 2	Level 1	Level 2	Level 3
Mean (mg/dL)	48	94	289
SD (mg/dL)	4.1	3.0	8.7
%CV	8.5	3.2	3.0
Lot 3	Level 1	Level 2	Level 3
Mean (mg/dL)	47	93	289
SD (mg/dL)	3.3	3.5	9.1
%CV	7.0	3.7	3.2

One Touch UltraSmart

Lot 1	Level 1	Level 2	Level 3
Mean (mg/dL)	47	94	290
SD (mg/dL)	3.5	3.6	9.5
%CV	7.4	3.8	3.3
Lot 2	Level 1	Level 2	Level 3
Mean (mg/dL)	48	93	291
SD (mg/dL)	3.8	3.2	10.3
%CV	7.9	3.5	3.5
Lot 3	Level 1	Level 2	Level 3
Mean (mg/dL)	47	94	291
SD (mg/dL)	3.4	3.1	9.7
%CV	7.2	3.3	3.3

b. Linearity/assay reportable range:

Linearity was evaluated using 11 venous blood samples with glucose concentrations adjusted to 15, 20, 80, 150, 250, 300, 350, 400, 510, 600 and 620 mg/dL and measured by YSI. Each sample was measured 10 times with 3 UniStrip test strip lots using calibration code 49 with the UniStrip test strips and the OneTouch®Ultra, OneTouch®Ultra2®, OneTouch UltraMini®, and OneTouch® UltraSmart® glucose meters. Mean values for each sample and glucose meter were calculated and compared to YSI values and used to perform linear regression. All of the individual sample results were within ±10% of the YSI sample results. The linear regression results are shown below.

	Slope	y-Int.	R^2	r
ONETOUCH® Ultra Blood Glucose Meters:	0.97	2.0	0.998	0.999
ONETOUCH® Ultra2 Blood Glucose Meters:	0.97	2.0	0.997	0.999
ONETOUCH® UltraMini Blood Glucose Meters:	0.97	2.8	0.997	0.999
ONETOUCH® UltraSmart Blood Glucose Meters:	0.98	0.5	0.998	0.999

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):

The UniStrip test strips are traceable to the NIST SRM #917b D-Glucose (Dextrose). The reference instrument used was the YSI 2300 Glucose Analyzer, which is calibrated by YSI 2747 Glucose Standard. The results of the capillary whole blood samples tested by ONETOUCH series Blood Glucose Meters Ultra, Ultra2, UltraMini and UltraSmart with UniStrip Blood Glucose Test Strips are compared with the results of the corresponded plasma samples tested by the calibrated YSI 2300 Glucose Analyzer.

The UniStrip test strip package insert instructs the user to check their device using the Prodigy® Control Solution. Expected control ranges for the low and high Prodigy Control Solutions are shown on the test strip vial. The controls were previously cleared in k060467.

Stability testing protocols and acceptance criteria for the UniStrip test strips shelf-life were provided. The manufacturer claims shelf life stability of 24 months and opened vial stability of 3 months when stored unopened at 4-30°C (relative humidity 10-90%) The real time and accelerated stability study protocols and acceptance critreria for these studies were reviewed and found to be adequate.

d. Detection limit:

See linearity in section M1b above.

e. Analytical specificity:

Interference testing was performed using three lots of UniStrip test strips and the OneTouch®Ultra, OneTouch®Ultra2®, OneTouch UltraMini®, and OneTouch® UltraSmart® meters by spiking venous blood to three glucose concentrations (40, 120, 340 mg/dL) and the potential interferent concentrations shown below. Each interferent and glucose concentration were tested in replicates of five with each lot and glucose meter then compared to the control sample. The sponsor defined no significant interference as ≤10% difference between individual interferent samples and the control sample. Results are shown below:

Interferant	Max Concentration with no significant interference
Acetaminophen	15 mg/dL
Ascorbic acid	3.0 mg/dL
Caffeine	100 mg/dL
Dopamine	6.0 mg/dL
Ephedrine	1.0 mg/dL
Gentisic Acid	10 mg/dL
L-dopa	20 mg/dL
Mannitol	5.0 mg/dL
Salicylates	60 mg/dL
Tetracycline	4.0 mg/dL
Cholesterol	700 mg/dL
Triglyceride	3000 mg/dL
Uric acid	15 mg/dL

The sponsor has the following limitations in the UniStrip test strip insert:

- Hematocrit is the percentage of red blood cells in the blood. Extremes in hematocrit may affect test results. Hematocrit levels below 30% may cause falsely high readings. Hematocrit levels over 55% may cause falsely low readings. If you do not know your hematocrit level, consult your healthcare professional.
- Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not affect results by more than 10%. However, more than normally high concentrations in blood may cause inaccurately high results.
- Lipemic samples: Cholesterol levels up to 700 mg/dL (18.1 mmol/L) and

triglycerides up to 3000 mg/dL (33.9 mmol/L) do not affect the results. Grossly lipemic patient samples have not been tested. They are not advised for testing with any OneTouch Ultra Meters.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A system accuracy study was performed to evaluate the system accuracy of the blood glucose system of ONETOUCH® Series Meters with UniStrip1 Blood Glucose Test Strips compared to Glucose Analyzer YSI 2300. Two each of the following meters were evaluated with three lots of UniStrip1 Blood Glucose Test Strips: OneTouch®Ultra, OneTouch®Ultra2®, OneTouch UltraMini®, and OneTouch® UltraSmart®. All meters were set to code 49 and 100 subjects with YSI blood glucose concentrations ranging from 47 to 444 mg/dL were evaluated over 10 days . Hematocrit for these samples was between 30% and 55%. To obtain samples with glucose < 50 mg/dL, samples were collected with an appropriate anticoagulant (EDTA) and allowed to incubate at room temperature to allow glucose to glycolyze. To obtain samples with glucose concentrations above 400 mg/dL, samples were collected with an appropriate anticoagulant (EDTA) and spiked with glucose. No more than three samples were adjusted with each of these procedures. For each test subject a fingerstick was performed by a healthcare professional and the sample was tested using one test strip for each glucose meter listed above. The procedure was repeated for palm and forearm test sites for all meters, except for the OneTouch®Ultra, which only tested finger and forearm sites. A healthcare professional drew a venous sample from each subject's arm to test hematocrit. An aliquot of this sample was used to test each subject's glucose concentration on the YSI 2300. The glucose concentration from each meter was compared to the YSI 2300. Results are summarized below.

Fingerstick

OneTouch® Ultra vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
11/18 (61%)	17/18 (94%)	18/18 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
38/82 (46%)	71/81 (85%)	79/82 (97%)	82/82 (100%)

OneTouch® Ultra2 vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
11/18 (61%)	17/18 (92%)	18/18 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
40/82 (49%)	70/82 (85%)	80/82 (98%)	82/82 (100%)

OneTouch® UltraMini vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
11/18 (61%)	17/18 (94%)	18/18 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
42/82 (51%)	66/82 (80%)	80/82 (98%)	81/82 (99%)

OneTouch® UltraSmart vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
10/18 (56%)	17/18 (94%)	18/18 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
42/82 (51%)	71/82 (87%)	81/82 (99%)	82/82 (100%)

Palm

OneTouch® Ultra2 vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
12/18 (67%)	17/18 (94%)	18/18 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
37/82 (45%)	63/82 (77%)	77/82 (95%)	81/82 (99%)

OneTouch® UltraMini vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
12/18 (67%)	16/18 (89%)	18/18 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
45/82 (55%)	69/82 (84%)	80/82 (98%)	81/82 (99%)

OneTouch® UltraSmart vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
12/18 (67%)	17/18 (94%)	17/18 (94%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
44/82 (54%)	69/82 (84%)	80/82 (98%)	82/82 (100%)

Forearm

OneTouch® Ultra vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
13/18 (72%)	17/18 (94%)	18/18 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
37/82 (41%)	68/82 (80%)	79/82 (97%)	82/82 (100%)

OneTouch® Ultra2 vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
9/18 (50%)	18/18 (100%)	18/18 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
37/82 (45%)	62/82 (76%)	81/82 (99%)	82/82 (100%)

OneTouch® UltraMini vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
11/18 (61%)	16/18 (89%)	18/18 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
43/82 (52%)	67/82 (82%)	79/82 (96%)	81/81 (99%)

OneTouch® UltraSmart vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
8/18 (446%)	178/18 (94%)	18/18 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
35/82 (43%)	67/82 (82%)	81/82 (99%)	81/82 (99%)

Linear regression analysis results are summarized below:

Fingerstick testing vs YSI 2300

	Slope	y-int.	R^2
ONETOUCH® Ultra Blood Glucose Meters:	0.997	1.18	0.981
ONETOUCH® Ultra2 Blood Glucose Meters:	0.992	-0.08	0.984
ONETOUCH® UltraMini Blood Glucose Meters:	0.979	1.18	0.982
ONETOUCH® UltraSmart Blood Glucose Meters:	0.992	0.38	0.985

AST Palm testing vs YSI 2300

	Slope	y-int.	R^2
ONETOUCH® Ultra2 Blood Glucose Meters:	0.994	-1.15	0.978
ONETOUCH® UltraMini Blood Glucose Meters:	0.982	1.03	0.983
ONETOUCH® UltraSmart Blood Glucose Meters:	0.987	0.33	0.984

AST Forearm testing vs YSI 2300

	Slope	y-int.	R^2
ONETOUCH® Ultra Blood Glucose Meters:	1.001	-2.06	0.981
ONETOUCH® Ultra2 Blood Glucose Meters:	1.015	-3.724	0.981
ONETOUCH® UltraMini Blood Glucose Meters:	0.976	1.96	0.981
ONETOUCH® UltraSmart Blood Glucose Meters:	0.986	1.22	0.981

b. Matrix comparison:

Not applicable

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):

A lay user study was performed with 152 volunteers between the ages of 15-80 years old. There were approximately equal numbers of male and female volunteers and they did not have experience performing blood glucose tests on themselves. Each volunteer read the user's guide before performing the testing. This was the only instruction provided. The users performed a fingerstick and measured their blood glucose. This was followed by the users performing palm and forearm sticks and testing, after which the technician performed a fingerstick and blood glucose measurement. A technician then performed a venous blood draw to measure hematocrit and glucose using the YSI-2300. The testing was performed with the UniStrip test strip and the OneTouch®Ultra, OneTouch®Ultra2®, OneTouch UltraMini®, and OneTouch® UltraSmart® meters. Results are summarized below.

Fingerstick results

ONETOUCH® Ultra versus YSI 2300

For glucose concentration<75 mg/dL

Within±5 mg/dL (Within±0.28 mmol/L)	Within±10 mg/dL (Within±0.56 mmol/L)	Within±15 mg/dL (Within±0.83 mmol/L)
15/21 (71%)	21/21 (100%)	21/21 (100%)

For glucose concentration≧75 mg/dL

Within±5 %	Within±10 %	Within±15 %	Within±20 %
89/131 (68)	112/131 (85%)	128/131 (98%)	131/131 (100%)

ONETOUCH® Ultra2 versus YSI 2300

For glucose concentration<75 mg/dL

Within±5 mg/dL (Within±0.28 mmol/L)	Within±10 mg/dL (Within±0.56 mmol/L)	Within±15 mg/dL (Within±0.83 mmol/L)
17/21 (81%)	21/21 (100%)	21/21 (100%)

For glucose concentration≧75 mg/dL

Within±5 %	Within±10 %	Within±15 %	Within±20 %
88/131 (67)	103/131 (79%)	126/131 (96%)	131/131 (100%)

ONETOUCH® UltraMini versus YSI 2300

For glucose concentration<75 mg/dL

Within±5 mg/dL (Within±0.28 mmol/L)	Within±10 mg/dL (Within±0.56 mmol/L)	Within±15 mg/dL (Within±0.83 mmol/L)
19/21 (90%)	21/21 (100%)	21/21 (100%)

For glucose concentration≧75 mg/dL

Within±5 %	Within±10 %	Within±15 %	Within±20 %
88/131 (67)	106/131 (81%)	125/131 (96%)	131/131 (100%)

ONETOUCH® UltraSmart versus YSI 2300

For glucose concentration<75 mg/dL

Within±5 mg/dL (Within±0.28 mmol/L)	Within±10 mg/dL (Within±0.56 mmol/L)	Within±15 mg/dL (Within±0.83 mmol/L)
16/21 (76%)	21/21 (100%)	21/21 (100%)

For glucose concentration≧75 mg/dL

Within±5 %	Within±10 %	Within±15 %	Within±20 %
98/131 (75%)	111/131 (85%)	131/131 (100%)	131/131 (100%)

AST Palm Results:

ONETOUCH® Ultra2 versus YSI 2300

For glucose concentration<75 mg/dL

Within±5 mg/dL (Within±0.28 mmol/L)	Within±10 mg/dL (Within±0.56 mmol/L)	Within±15 mg/dL (Within±0.83 mmol/L)
17/21 (81%)	17/21 (81%)	21/21 (100%)

For glucose concentration≧75 mg/dL

Within±5 %	Within±10 %	Within±15 %	Within±20 %
85/131 (65%)	105/131 (80%)	123/131 (94%)	131/131 (100%)

ONETOUCH® UltraMini versus YSI 2300

For glucose concentration<75 mg/dL

Within±5 mg/dL (Within±0.28 mmol/L)	Within±10 mg/dL (Within±0.56 mmol/L)	Within±15 mg/dL (Within±0.83 mmol/L)
18/21 (86%)	21/21 (100%)	21/21 (100%)%)

For glucose concentration≧75 mg/dL

Within±5 %	Within±10 %	Within±15 %	Within±20 %
88/131 (67%)	109/131 (83%)	124/130 (95%)	128/131 (98%)

ONETOUCH® UltraSmart versus YSI 2300

For glucose concentration<75 mg/dL

Within±5 mg/dL (Within±0.28 mmol/L)	Within±10 mg/dL (Within±0.56 mmol/L)	Within±15 mg/dL (Within±0.83 mmol/L)
17/21 (81%)	20/21 (95%)	21/21 (100%)

For glucose concentration≧75 mg/dL

Within±5 %	Within±10 %	Within±15 %	Within±20 %
96/131 (738%)	111/131 (85%)	126/131 (96%)	131/131 (100%)

AST Forearm results

ONETOUCH® Ultra versus YSI 2300

For glucose concentration<75 mg/dL

Within±5 mg/dL (Within±0.28 mmol/L)	Within±10 mg/dL (Within±0.56 mmol/L)	Within±15 mg/dL (Within±0.83 mmol/L)
20/21 (95%)	21/21 (100%)	21/21 (100%)

For glucose concentration≧75 mg/dL

Within±5 %	Within±10 %	Within±15 %	Within±20 %
98/131 (75%)	107/131 (82%)	123/131 (94%)	129/131 (98%)

ONETOUCH® Ultra2 versus YSI 2300

For glucose concentration<75 mg/dL

Within±5 mg/dL (Within±0.28 mmol/L)	Within±10 mg/dL (Within±0.56 mmol/L)	Within±15 mg/dL (Within±0.83 mmol/L)
18/21 (86%)	21/21 (100%)	21/21 (100%)

For glucose concentration≧75 mg/dL

Within±5 %	Within±10 %	Within±15 %	Within±20 %
89/131 (68%)	104/131 (79%)	122/131 (93%)	128/131 (98%)

ONETOUCH® UltraMini versus YSI 2300

For glucose concentration<75 mg/dL

Within±5 mg/dL (Within±0.28 mmol/L)	Within±10 mg/dL (Within±0.56 mmol/L)	Within±15 mg/dL (Within±0.83 mmol/L)
18/21 (86%)	20/21 (95%)	21/21 (100%)

For glucose concentration≧75 mg/dL

Within±5 %	Within±10 %	Within±15 %	Within±20 %
85/131 (65%)	104/131 (79%)	123/131 (94%)	139/131 (98%)

ONETOUCH® UltraSmart versus YSI 2300

For glucose concentration<75 mg/dL

Within±5 mg/dL (Within±0.28 mmol/L)	Within±10 mg/dL (Within±0.56 mmol/L)	Within±15 mg/dL (Within±0.83 mmol/L)
16/21 (76%)	18/21 (86%)	21/21 (100%)

For glucose concentration≧75 mg/dL

Within±5 %	Within±10 %	Within±15 %	Within±20 %
94/131 (72%)	118/131 (90%)	130/131 (99%)	131/131 (100%)

Linear regression analysis results are summarized below:

AST Palm testing vs YSI 2300

	Slope	y-int.	R^2
ONETOUCH® Ultra2 Blood Glucose Meters:	1.020	0.03	0.977
ONETOUCH® UltraMini Blood Glucose Meters:	1.023	-1.54	0.976
ONETOUCH® UltraSmart Blood Glucose Meters:	1.047	-4.28	0.979

AST Forearm testing vs YSI 2300

	Slope	y-int.	R^2
ONETOUCH® Ultra Blood Glucose Meters:	1.008	-0.35	0.976
ONETOUCH® Ultra2 Blood Glucose Meters:	1.019	-1.06	0.980
ONETOUCH® UltraMini Blood Glucose Meters:	1.009	-0.57	0.971
ONETOUCH® UltraSmart Blood Glucose Meters:	1.022	-0.14	0.983

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   The package insert states the following:

   Reference values: Please consult your physician to establish your target ranges. The American Diabetes Association (ADA) suggests the following targets for most nonpregnant adults without diabetes. More or less stringent goals may be appropriate for each individual.

   Glycemic control Time of Day ADA Suggested Reading

   Preprandial plasma glucose 70–100 mg/dl (before a meal)

   Postprandial plasma glucose <140 mg/dl (after a meal)

   Source: American Diabetes Association. Standards of medical care in diabetes - 2012. 2012;35 (supp.1 Diabetes Care):S11-563.

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

1. Software validation testing was performed demonstrating that the error codes displayed by the meters functioned as intended with the UniStrip test strips.

2. The package insert instructs the use to call 1.888.729.9674 if the user needs any additional assistance, if the test strips vial is open or damaged, or if the instructional

materials or results seem unclear. The insert states that the firm can be contacted 24 hours a day / 7 days a week.

3. Hematocrit Study: The effect of different hematocrit levels on the performance of the UniStrip test strip with the OneTouch®Ultra, OneTouch®Ultra2®, OneTouch UltraMini®, OneTouch® UltraSmart®meters was evaluated using venous whole blood samples with hematocrit levels of 25, 30, 35, 45, 55 and 60% spiked with glucose to 5 concentrations (approximately 40, 80, 130, 200 and 320 mg/dL). Each sample was then tested in replicates of 10 using each meter type with three lots of UniStrip test strips and the values were compared with those obtained from YSI analyzer. The % biases relative to YSI were acceptable within the claimed hematocrit range of 30 to 55%.

4. The UniStrip test strip labeling states that the test strips can be used at a temperature range of 6-44°C and a relative humidity (RH), range of 10-90%. In order to demonstrate this performance, OneTouch®Ultra, OneTouch®Ultra2®, OneTouch UltraMini®, OneTouch® UltraSmart® meters and the UniStrip test strips were placed in environmental chambers with the following temperature/relative humidity combinations: 6°C/10% RH, 6°C/90% RH, 25°C/10% RH, 25°C/90% RH, 44°C/10% RH and 44°C/90% RH. Fresh venous blood samples with glucose concentrations of approximately 50, 150 and 315 mg/dL were tested five times with each glucose meter model at all of the temperature/RH combinations shown above and the results from each measurement were compared to the YSI values for each sample. The results from each measurement were within the sponsor's acceptance criteria. These results demonstrate that the performance of the UniStrip test strips with the claimed meters is unaffected by the temperature and humidity ranges specified in the device labeling.

5. Altitude Study: The effect of altitude on the performance of the UniStrip test strip with the OneTouch®Ultra, OneTouch®Ultra2®, OneTouch UltraMini®, OneTouch® UltraSmart®meters was evaluated using venous whole blood samples spiked with glucose to 5 concentrations (approximately 40, 80, 130, 200 and 320 mg/dL). Each meter model was used to test each sample five times at altitudes of 298, 3,608, 7,575 and 10,745 feet above sea level. The results from each measurement were compared to the YSI values for each sample. The results from each measurement were the sponsor's acceptance criteria. These results demonstrate that the performance of the UniStrip test strips with the claimed meters is unaffected by altitudes up to 10,745 feet.

   The sponsor has the following limitations in the UniStrip test strip insert:

   - UniStrip1 Test Strips may be used at altitudes up to 10,000 feet (3048 meters) without an effect on test results. Accurate results were shown in clinical studies

performed at heights up to 5,280 feet (1609 meters) and in studies simulating heights up to 10,745 feet (3275 meters).

- Patients going through oxygen therapy may yield falsely low results.

6. The sponsor performed a readability assessment of the test strip package insert and the results showed the insert was readable at an 8th grade level.

7. The sponsor evaluated the minimum blood sample size required by testing sample volumes ranging from 0.5 to 2.0 µl on each meter. 5 glucose concentrations were tested ranging from 40~400 mg/dL, as determined by the YSI. Appropriate sample volume was determined if the meter results matched the YSI results. The data shows that sample volume of ≥0.8 µL is the smallest volume to produce acceptable results.

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.