

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM**

A. 510(k) Number:

k160038

B. Purpose for Submission:

Modification to alternative blood glucose test strips (calibration code 49) for use with LifeScan One Touch Ultra2, UltraSmart, UltraMini and Ultra blood glucose meters. Date has been extended for use of these test strips with the Ultra2, UltraSmart and UltraMini meters to those meters purchased before April 2016. The date for use of these strips with the OneTouch Ultra meters remains as those purchased before October 2012. Also, to change the name of the strips from UniStrip1Blood Glucose Test Strips to UniStrip1 Generic Blood Glucose Tests Strips, extend the test strip temperature storage range for all 4 meters and rename the previously cleared (k060467) Prodigy Control Solutions as the UniStrip Control Solutions.

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative Amperometric assay (Glucose Oxidase)

E. Applicant:

OK Biotech Co., Ltd.

F. Proprietary and Established Names:

UniStrip1 Generic Blood Glucose Test Strips

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1345, Glucose test system

21 CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:

Class II

Class I (reserved)

3. Product code:

NBW, System, Test, Blood Glucose, Over The Counter

CGA, Glucose Oxidase, Glucose

JJX, Single (specified) analyte controls (assayed and unassayed)

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The UniStrip1 Generic Blood Glucose Test Strips are used with the OneTouch Ultra2, OneTouch UltraMini and One-Touch UltraSmart meters purchased before April 2016, and the OneTouch® Ultra®, purchased before October 2012, set at calibration code 49, for measuring glucose (sugar) in whole capillary blood. The strips are 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 Generic Blood Glucose 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).

The UniStrip Control Solutions are for use with the UniStrip1 Generic Blood Glucose Test Strips and One Touch Ultra meters to check that the meters and test strips are working together properly and that the test is performing correctly.

3. Special conditions for use statement(s):

- For over-the-counter use
- Do not use for screening purposes
- Do not use for the diagnosis of diabetes or for testing of neonates
- Test results may be falsely low if the patient is severely dehydrated, in shock, or in a hyperosmolar state (with or without ketosis).
- Patients going through oxygen therapy may yield falsely low results
- These test strips should not be used with meters to test critically ill patients.
- Test strips are for single use only
- 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.
- Do not use at altitudes greater than 10,000 feet (3048 meters)
- Hematocrit levels below 30% may cause falsely high reading. Hematocrit levels over 55% may cause falsely low reading. If you do not know your hematocrit level, consult your doctor or nurse.

4. Special instrument requirements:

LifeScan OneTouch Ultra2, UltraSmart and UltraMini Blood Glucose Meters purchased before April 2016, and One Touch Ultra Blood Glucose Meter purchased before October 2012, with test strip calibration code 49.

I. Device Description:

The UniStrip1 Generic Blood Glucose Test Strips are used with the OneTouch Ultra2, OneTouch UltraMini and OneTouch UltraSmart glucose monitoring meters purchased before April 2016, and with the One Touch Ultra purchased before October 2012, for quantitatively measuring glucose in fresh capillary whole blood. UniStrip1 Generic Blood Glucose Test Strips are only for use with calibration code 49.

The UniStrip1 Generic Blood Glucose Test Strip package insert instructs the user to check their device using UniStrip Control Solutions. The UniStrip Control Solutions, Levels 1 and 2, are identical to the Prodigy Control Solutions cleared in k060467 except for the names.

J. Substantial Equivalence Information:

1. Predicate device name(s):

UniStrip1 Test Strips
Prodigy Control Solutions

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

k113135
k064667

3. Comparison with predicate:

Similarities		
Item	Predicate (k113135)	Candidate (k160038)
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 (on Ultra2, UltraMini and UltraSmart) Fingertip and forearm only on Ultra	Same
Detection method	Amperometry	Same
Enzyme	Glucose Oxidase (Aspergillus niger)	Same
Sample volume	1.0 uL	Same
Reaction time	5 seconds	Same
Measurement range	20-600 mg/dL	Same
Hematocrit range	30 - 55%	Same
Calibration code	49 only	Same

Differences		
Item	Predicate (k113135)	Candidate (k160038)
Meter specifications	One Touch Ultra, Ultra2, UltraMini, UltraSmart meters, purchased before October 2012	One Touch Ultra2, UltraMini, UltraSmart meters, purchased before April 2016, and One Touch Ultra, purchased before October 2012
Strip Storage Conditions	4-30 °C (39-86 °F)	4-40 °C (39-104 °F)

Similarities and Differences for Control Solutions		
Item	Predicate Device Prodigy Control Solutions, k060467	Candidate Device UniStrip Control Solutions
Intended use/Indications for Use	Used with Prodigy meter and Prodigy Glucose Test Strips to check that meters and test strips are working together properly and that test is performing correctly	Used with UniStrip1 Generic Blood Glucose Test Strips and OneTouch Ultra meters to check that meters and test strips are working together properly and that test is performing correctly
Matrix	Same	Viscosity-adjusted, aqueous liquid.
Levels	Same	Two levels, Level 1 and 2

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

1. CLSI EP7-A2. Interference Testing in Clinical Chemistry; Approved Guideline (2007).
2. CLSI EP5-A3. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline (2015).
3. CLSI EP6-A. Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2014)

L. Test Principle:

Glucose in the blood sample mixes with glucose oxidase on the UniStrip1 Generic Blood Glucose Test Strip and a small electrical current is generated and measured by the meter(s) and displayed as a blood glucose results. The strength of the current changes proportionally with the amounts of glucose in the blood sample.

M. Performance Characteristics (if/when applicable):

The sponsor states that the following performance evaluations provided for the UniStrip1 Generic Blood Glucose Test Strips were obtained using the 3 claimed meters for which the claim dates are changing (LifeScan OneTouch Ultra 2, One Touch UltraSmart and OneTouch UltraMini) purchased before April 2016. The compatibility of the test strips with the One Touch Ultra meter has not been reevaluated since the claimed date period has remained the same as originally cleared in k113135, i.e. as purchased before October 2012. The sponsor states that UniStrip1 Generic Blood Glucose Test Strip calibration code 49 was used in each of the performance evaluations.

1. Analytical performance:

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 1 Generic Blood Glucose Test Strips and the OneTouch Ultra2, OneTouch UltraMini and OneTouch UltraSmart glucose meters. Three UniStrip1Generic Blood Glucose Test Strip 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 25 tests for each glucose meter model and test strip lot combination for each glucose concentration. The results are summarized below.

One Touch Ultra2

Glucose Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	42.0	1.4	3.3
	2	41.8	1.5	3.5
	3	41.7	1.5	3.5

51-110	1	79.2	1.4	1.8
	2	78.9	1.4	1.8
	3	79.0	1.5	1.9
111-150	1	128.9	2.6	2.0
	2	129.0	2.6	2.0
	3	128.3	2.7	2.1
151-250	1	199.0	3.6	1.8
	2	199.1	3.9	2.0
	3	198.8	4.3	2.2
251-400	1	324.8	7.2	2.2
	2	324.5	6.1	1.9
	3	322.6	7.2	2.2

One Touch UltraMini

Glucose Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	41.7	1.4	3.2
	2	42.3	1.4	3.3
	3	41.9	1.4	3.4
51-110	1	79.1	1.5	1.9
	2	79.2	1.5	1.9
	3	78.9	1.3	1.7
111-150	1	128.4	2.5	1.9
	2	129.4	2.7	2.1
	3	129.3	2.8	2.2
151-250	1	198.7	4.6	2.3
	2	198.4	4.3	2.2
	3	199.1	4.4	2.2
251-400	1	326.3	8.2	2.5
	2	325.6	9.3	2.9
	3	322.2	8.8	2.7

One Touch UltraSmart

Glucose Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	42.5	1.3	3.1
	2	42.0	1.4	3.2
	3	41.6	1.4	3.4
51-110	1	79.0	1.2	1.5
	2	78.8	1.1	1.5
	3	79.5	1.4	1.8
111-150	1	129.2	2.8	2.2
	2	129.1	2.7	2.1
	3	130.0	2.6	2.0
151-250	1	199.0	4.5	2.3
	2	198.3	4.4	2.2
	3	199.0	4.0	2.0

251-400	1	324.1	6.5	2.0
	2	325.5	7.9	2.4
	3	325.6	7.6	2.3

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 1 Generic Blood Glucose Test Strips and the OneTouchUltra2, OneTouch UltraMini, and OneTouch UltraSmart glucose meters. Five different meters for each model type above were each used to test each sample in singlicate with 3 test strip lots. This resulted in 5 tests for each glucose meter model and test strip lot combination each day for each glucose concentration tested over ten days for a total of 50 tests. Results are summarized below.

OneTouch Ultra 2

Control Level	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1 (30-50 mg/dL)	39.0	0.8	2.1
Level 2 (96-144 mg/dL)	118.9	3.2	2.7
Level 3 (250-420 mg/dL)	260.5	8.0	3.1

OneTouch UltraMini

Control Level	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1 (30-50 mg/dL)	39.0	0.8	2.1
Level 2 (96-144 mg/dL)	119.2	3.1	2.6
Level 3 (250-420 mg/dL)	259.7	7.7	3.0

OneTouch UltraSmart

Control Level	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1 (30-50 mg/dL)	39.0	0.8	2.1
Level 2 (96-144 mg/dL)	119.0	3.3	2.8
Level 3 (250-420 mg/dL)	260.3	8.0	3.1

b. Linearity/assay reportable range:

Linearity was evaluated using 13 venous blood samples with glucose concentrations adjusted to 20.7, 50.3, 98.2, 151, 199, 250, 305, 351, 401, 445, 501, 546, and 601 mg/dL as measured by YSI. Each sample was measured 10 times with 3 UniStrip1 Generic Blood Glucose Test Strip lots using calibration code 49 and the 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. The linear regression results are shown below.

Meter	Slope	Intercept	R ²	r
OneTouch Ultra2	0.9862	2.87	0.9994	0.9996
OneTouch UltraMini	0.9898	2.06	0.9997	0.9998
OneTouch UltraSmart	0.9860	2.69	0.9996	0.9997

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 UniStrip1 Generic Blood Glucose Test Strips are traceable to the NIST SRM #917c glucose standard. The method comparison study was performed using the candidate devices and YSI as the reference method (see Section 2.a.)

Test Strip Stability:

Stability of the UniStrip1 Generic Blood Glucose Test Strips was assessed using real time and accelerated testing. Protocols and acceptance criteria for these studies were reviewed and found to be acceptable to support the manufacturer claimed shelf life stability of 24 months and opened vial stability of 3 months when stored at 39°F-104°F (4-40°C) and relative humidity of 10-90%.

Control Solution Value Assignment and Stability:

The UniStrip Control Solutions Level 1 and Level 2 were previously cleared (k060467) and are identical except in name. The value assignment protocol and the stability protocols and acceptance criteria were reviewed under k060467 and found to be acceptable to support the claims that the closed control solution vials are stable for 18 months and the opened control solution vials are stable for 90 days after opening when stored at the recommended storage conditions of 39°F-86°F (4°C-30°C).

d. Detection limit:

See linearity in section M1b above.

e. Analytical specificity:

Interference testing was performed to evaluate exogenous and endogenous substances using three lots of UniStrip1 Generic Blood Glucose Test Strips and the OneTouch Ultra2, OneTouch UltraMini, and OneTouch UltraSmart meters. Venous blood was spiked to two glucose levels (50-100 and 250-350 mg/dL) and the potential interferent concentrations were tested at 4 levels ranging from therapeutic (or physiological) to toxic (or pathological). Each interferent and glucose concentration were tested in replicates of five with each test strip lot and compared to the control sample containing no added interferent. The sponsor defined no significant interference as $\leq 10\%$ difference between individual interferent samples and the control sample. Results are shown below:

Potential Interferent	Highest concentration tested at which no significant interference is observed (mg/dL)
Acetaminophen	15
Ascorbic acid	3
Bilirubin	90
Caffeine	100
Cholesterol	700
Creatinine	5
Dopamine	6
Ephedrine	1
Galactose	900
Gentisic acid	10
Glutathione	53
Hemoglobin	500
Ibuprofen	50
Mannitol	5
L-dopa	20
Maltose	900
Methyldopa	3
Tetracycline	4
Salicylate	60
Tolazamide	100
Tolbutamide	400
Triglyceride	3000
Uric acid	15
Xylose	100

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

- Vitamin C (ascorbic acid > 3.0 mg/dL), might affect the reliability of your blood glucose results. If you are taking Vitamin C your glucose results may not be reliable. If you are unsure, then ask your doctor.
- Acetaminophen > 15 mg/dL might affect the reliability of your blood glucose results. If you are taking Tylenol your glucose results may not be reliable. If you are unsure, then ask your doctor.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

To assess the performance of the UniStrip1 Generic Blood Glucose Test Strips and the OneTouch Ultra2, OneTouch UltraMini, and OneTouch UltraSmart meters in the

hands of the intended users the sponsor performed a study with 140 English speaking lay user participants. Using only the written labeling materials, the users performed fingerstick, palm and forearm testing, after which a technician obtained venous blood to measure glucose using the YSI-2300. Results were analyzed by comparing the results from the UniStrip1 Generic Blood Glucose Test Strips and the OneTouch Ultra2, OneTouch UltraMini, and OneTouch UltraSmart meters obtained by the lay users against the YSI 2300 reference value. The range of samples tested was 47-467 mg/dL as measured by the YSI. Results are summarized below:

Fingerstick

OneTouch Ultra2 vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
25/40 (62.5%)	37/40 (92.5%)	40/40 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
66/100 (66%)	92/100 (92%)	97/100 (97%)	100/100 (100%)

OneTouch UltraMini vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
26/40 (65%)	34/40 (85%)	40/40 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
68/100 (68%)	93/100 (93%)	99/100 (99%)	100/100 (100%)

OneTouch UltraSmart vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
26/40 (65%)	36/40 (90%)	40/40 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
70/100 (70%)	91/100 (91%)	96/100 (96%)	100/100 (100%)

Palm

OneTouch Ultra2 vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
24/40 (60%)	36/40 (90%)	40/40 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
72/100 (72%)	92/100 (92%)	98/100 (98%)	100/100 (100%)

OneTouch UltraMini vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
25/40 (62.5%)	34/40 (85%)	40/40 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
66/100 (100%)	92/100 (92%)	97/100 (97%)	100/100 (100%)

OneTouch UltraSmart vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
26/40 (65%)	35/40 (87.5%)	40/40 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
64/100 (64%)	89/100 (89%)	97/100 (97%)	100/100 (100%)

Forearm

OneTouch Ultra vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
26/40 (65%)	34/40 (85%)	40/40 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
62/100 (62%)	89/100 (89%)	97/100 (97%)	100/100 (100%)

OneTouch UltraMini vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
26/40 (65%)	34/40 (85%)	40/40 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
65/100 (65%)	92/100 (92%)	96/100 (96%)	100/100 (100%)

OneTouch UltraSmart vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
25/40 (62.5%)	37/40 (92.5%)	40/40 (100%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
64/100 (64%)	92/100 (92%)	96/100 (96%)	100/100 (100%)

Linear regression analysis results are summarized below:

Fingerstick testing vs YSI 2300

	Slope	intercept	R ²
OneTouch Ultra2	0.9783	1.4938	0.9829
OneTouch UltraMini	0.9759	1.6860	0.9849
OneTouch UltraSmart	0.9806	1.3315	0.9853

AST Palm testing vs YSI 2300

	Slope	intercept	R ²
OneTouch Ultra2	0.9718	2.3621	0.9876
OneTouch UltraMini	0.9928	-0.7268	0.9848
OneTouch UltraSmart	0.9924	-0.8447	0.9849

AST Forearm testing vs YSI 2300

	Slope	intercept	R ²
OneTouch Ultra2	0.9945	-0.8910	0.9865
OneTouch UltraMini	0.9773	1.2990	0.9856
OneTouch UltraSmart	1.0152	-2.6014	0.9884

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):*

See Section M.2.a

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The fasting adult blood glucose range for a person without diabetes:

Before meals <100 mg/dL (5.6 mmol/L)

After meals: <140 mg/dL (7.8 mmol/L)

Source: American Diabetes Association. Standards of medical care in diabetes - 2016
2016;39 (supp.1 Diabetes Care):S16.

N. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

1. **Altitude study:** The effect of altitude on the performance of the UniStrip1 Generic Blood Glucose Test Strips with the OneTouchUltra2, OneTouch UltraMini, and OneTouch UltraSmart meters was evaluated using venous whole blood samples spiked with glucose to 5 concentrations (43, 82, 131, 199 and 318 mg/dL). Each meter model was used to test each sample five times on 3 test strip lots at altitudes of 298, 4790, and 11,161 feet above sea level. The results from each measurement were compared to the YSI values for each sample. The results demonstrate acceptable bias to YSI and support the labeling claims that altitudes up to 10,000 feet have no significant effect on performance of the UniStrip1 Generic Blood Glucose Test Strips with the claimed meters.
2. **Hematocrit study:** The effect of different hematocrit levels on the performance of the UniStrip1 Generic Blood Glucose Test Strips with the OneTouch Ultra2, OneTouch UltraMini, and OneTouch UltraSmart meters was evaluated using venous whole blood samples with hematocrit levels of 25, 30, 42, 50 and 60% spiked with glucose to 3 concentrations (40, 139, and 315 mg/dL). Each sample was then tested in replicates of 10 using each meter type with three lots of UniStrip1 Generic Blood Glucose 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%.

3. **Sample volume study:** A sample volume study was performed using venous whole blood samples spiked to five glucose concentrations (40, 79, 113, 179, and 220 mg/dL, as measured by YSI) to evaluate the effect of different sample volumes (0.6, 0.8, 0.9, 1.0, 1.1, 1.3, and 1.5 μ L) on the performance of the device. Results at each sample volume were compared to the corresponding YSI values. Three lots of test strips and 10 measurements per lot were used on the OneTouch Ultra2, OneTouch UltraMini, and OneTouch UltraSmart meters. Results from these studies support the claimed minimum sample volume of 1.0 μ L.
4. **Operating Conditions:** The operating temperature range and relative humidity range (RH) were evaluated by placing OneTouch Ultra2, OneTouch UltraMini, and OneTouch UltraSmart meters, with the UniStrip1 Generic Blood Glucose Test Strips, 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 48, 154 and 318 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. These results support the sponsor's claims in the labeling that the UniStrip 1 Generic Blood Glucose test strips with the claimed meters can be used in the temperature and humidity ranges specified in the device labeling, that is 42-111°F (6-44°C) and 10-90%RH.
5. **Readability Assessment:** A Flesch-Kinkaid reading level assessment was conducted demonstrating that the test strip and control inserts were written at or below an 8th grade reading level.
6. **Customer Support:** The user is instructed to call 1.866.889.6229 for additional assistance, Monday - Friday, 9am - 5pm EST.
7. **Software validation:** Software validation testing was performed demonstrating that the error codes displayed by the OneTouch Ultra2, OneTouch UltraMini and OneTouch UltraSmart meters functioned as intended with the UniStrip1 Generic Blood Glucose Test Strips when set at calibration code 49.

O. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

P. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.