510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM

A. 510(k) Number:

k162430

B. Purpose for Submission:

Modification to alternative blood glucose test strips (calibration code 49) for use with LifeScan One Touch Ultra meters purchased before April 2016.

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

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™ Generic Blood Glucose Test Strips are used with the OneTouch® Ultra®, OneTouch® Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmart® meters purchased before April 2016, 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.

   The 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).

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 Ultra Blood Glucose Meters purchased before April 2016, and with test strip calibration code 49.

I. Device Description:

The UniStrip1 Generic Blood Glucose Test Strips are used with the One Touch Ultra glucose monitoring meters purchased before April 2016. UniStrip1 Generic Blood Glucose Test Strips are only for use with calibration code 49.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   UniStrip1 Generic Blood Glucose Test Strips

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

   k160038

3. Comparison with predicate:

Similarities		
Item	Predicate (k160038)	Candidate (k162430)
Indications for Use	Quantitative determination of glucose concentrations in blood as an aid in monitoring effectiveness of diabetes control.	Same
Enzyme	Glucose oxidase (Aspergillus niger)	Same
Specimen Type	Capillary whole blood from fingertip and alternative sites (palm, forearm and upper-arm) (Use of palm AST is not to be done with OneTouch® Ultra® meter).	Same
Sample Volume	1.0 µL	Same
Operating Conditions	43 – 111°F (6 - 44°C) 10 - 90% R.H.	Same
HCT Range	30 - 55%	Same
Measuring Range	20 - 600 mg/dL	Same
Measuring time	5 seconds	Same
Strip Storage Temperature	39 – 104°F (4 – 40°C)	Same

Differences		
Item	Predicate (k160038)	Candidate (k162430)
Meter specifications	One Touch Ultra2, UltraMini, UltraSmart meters, purchased before April 2016, and One Touch Ultra, purchased before October 2012	One Touch Ultra2, UltraMini, UltraSmart, OneTouch Ultra meters, purchased before April 2016

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 OneTouch Ultra for which the claimed manufacturing dates are changing (One Touch Ultra) purchased before April 2016. The sponsor states that UniStrip1 Generic Blood Glucose 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 1 Generic Blood Glucose Test Strips and the One Touch Ultra glucose meters. Three UniStrip1Generic Blood Glucose Test Strip lots were used with each blood glucose meter. Five different meters were 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 and test strip lot combination for each glucose concentration. The results are summarized below.

One Touch Ultra

Glucose Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	42.9	1.4	3.2
	2	43.0	1.4	3.2
	3	42.9	1.5	3.5
51-110	1	79.1	1.5	1.8
	2	79.0	1.5	1.9
	3	79.1	1.4	1.8
111-150	1	129.2	2.8	2.1
	2	128.8	2.7	2.1
	3	129.0	2.5	1.9
151-250	1	201.5	4.1	2.0
	2	201.3	4.2	2.1
	3	201.3	4.7	2.3
251-400	1	325.6	6.8	2.1
	2	324.2	7.8	2.4
	3	324.2	6.8	2.1

Between-run precision was performed over ten days using three blood glucose control concentrations. Each sample was tested using calibration code 49 with the OneTouch Ultra glucose meter. Five different meters were 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

Control Level	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1 (30-50 mg/dL)	39.0	1.4	3.6
Level 2 (96-144 mg/dL)	119	4.6	3.8
Level 3 (250-420 mg/dL)	257.6	10	3.9

b. *Linearity/assay reportable range:*
Linearity was evaluated using 13 venous blood samples with glucose concentrations adjusted to 20.3, 49.9, 98.7, 150.3, 198.8, 250, 299.0, 350.5, 399.3, 451.3, 510.5, 551.0, and 606.8 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 Ultra glucose meter. 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
Lot I	0.994	-1.0434	0.9988	0.9994
Lot II	1.0037	0.6514	0.9985	0.99925
Lot III	1.0039	0.389	0.9991	0.99955
All Lots	1.0006	-0.0098	0.9995	0.99975

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%.

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 Ultra meter. 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. Results are shown below:

Potential Interferent	Highest concentration tested at which no significant interference is observed (mg/dL)
Acetaminophen	8
Ascorbic Acid	2
Caffeine	50
Bilirubin	50

Potential Interferent	Highest concentration tested at which no significant interference is observed (mg/dL)
Cholesterol	500
Creatinine	3
Dopamine	3
Galactose	500
Gentisic acid	5
Glutathione	25
Haemoglobin	250
Ephedrine	0.1
Ibuprofen	20
Mannitol	2.5
L-dopa	10
Maltose	500
Methyldopa	1
Salicylate	40
Tetracycline	1
Tolazamide	50
Tolbutamide	400
Triglyceride	1500
Uric acid	10
Xylose	50

Ascorbic acid (vitamin C) in concentrations > 2mg/dL may cause significant interference (affect the results by greater than 10%) resulting in an inaccurate result.

If you are taking acetaminophen or acetaminophen containing medications (Tylenol, certain cold and flu remedies, or certain prescription drugs) then your blood glucose results may not be accurate (blood concentrations >8 mg/dL). If you are unsure, than ask your healthcare professional.

If you are taking ibuprofen or ibuprofen containing medications then your blood glucose results may not be accurate (blood concentrations >20 mg/dL). If you are unsure, than ask your healthcare professional.

If you have a disease or condition that elevates your blood uric acid level (>10mg/dL), such as gout, your blood glucose results may not be reliable. If you are unsure, then ask your healthcare professional.

If you undergo a Xylose Absorption test, your blood glucose results may be not reliable following the test. You should not use theUniStrip1 Generic Blood Glucose Test Strips following Xylose Absorption tests. If you are unsure, then ask your healthcare professional.

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 Ultra meter in the hands of the intended users the sponsor performed a study with 100 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 meters obtained by the lay users against the YSI 2300 reference value. The range of samples tested was 45-544 mg/dL as measured by the YSI. 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
13/20 (65.0%)	17/20 (85%)	20/20 (100.0%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
52/80 (65%)	71/80 (88.8%)	80/80 (100%)	80/80 (100.0%)

Forearm
OneTouch Ultra vs YSI-2300

Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
13/20 (65.0%)	18/20 (90%)	20/20 (100.0%)

Glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
50/80 (62.5%)	73/80 (91.3%)	80/80 (100%)	80/80 (100.0%)

Linear regression analysis results are summarized below:

OneTouch Ultra vs YSI 2300

	Slope	intercept	R^2
Fingerstick	0.9982	1.2235	0.9827
Forearm	1.0091	1.4813	0.9828

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[1]:

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 OneTouch Ultra meter 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 UniStrip1Generic 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 Ultra meter 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 (41.2, 76.8, 113, 176, and 337 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 μL) 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 Ultra meter. Results from these studies support the claimed minimum sample volume of 1.0 μL.

4. **Operating Conditions:** The operating temperature range and relative humidity range (RH) were evaluated by placing OneTouch 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 49, 152 and 317 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 Ultra meter 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.