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

A. 510(k) Number:

k103542

B. Purpose for Submission:

Alternative blood glucose test strips for use with LifeScan OneTouch Ultra, Ultra2 and UltraMini blood glucose meters purchased before July 2010 with test strip calibration codes 4, 10, and 13.

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative Amperometric assay (Glucose Oxidase)

E. Applicant:

Shasta Technologies, LLC

F. Proprietary and Established Names:

GenStrip 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:

   GenStrip Test Strips with calibration codes 4, 10 and 13 are for use with OneTouch Ultra, Ultra2 and UltraMini Meter purchased before July 2010. They are used to quantitatively measure glucose in fresh capillary whole blood samples taken form the finger, forearm or palm. 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. The system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

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 and UltraMini blood glucose meters purchased before July 2010 and GenStrip test strips with calibration codes 4, 10, and 13.

I. Device Description:

The GenStrip blood glucose test strips with calibration codes 4, 10, and 13 are alternative blood glucose test strips for use with LifeScan OneTouch Ultra, Ultra2 and UltraMini blood glucose meters purchased before July 2010. Test strips are packaged in vials of 50. Each test strip contains glucose oxidase (Aspergillus niger, potassium ferricyanide, buffer and other non-reactive ingredients.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   OneTouch Ultra Blood Glucose Monitoring System; LifeScan

2. Predicate k number(s):

   k002134

3. Comparison with predicate:

Similarities and Differences of the Blood Glucose System		
Item	Predicate Device OneTouch Ultra (k002134)	Candidate Device GenStrip Test Strips
Intended Use/Indications for Use	Intended to be used for quantitative measurement of glucose in fresh capillary whole blood. Intended for use outside the body (in vitro diagnostic use) by diabetics as an aid to monitor the effectiveness of diabetes control.	Same
User	Diabetics at home and healthcare professionals in the clinical setting	Diabetics at home
Detection method	Amperometry	Same
Enzyme	Glucose Oxidase	Same
Test range	20 - 600 mg/dL	Same
Hematocrit range	30 - 55%	Same
Sample type	Capillary whole blood	Same
Sample sites	Fingertip, forearm, palm	Same
Sample volume	1 µL	Same
Altitude Claim	10,000 feet	9945 feet
'Lo' and 'Hi' detection	<20 mg/dL and >600 mg/dL glucose	Same
Insufficient sample detection	Yes with associated error code	Same
Used strip detection	Yes with associated error code	Same
Incorrect sample application detection	Yes with associated error code	Same

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

- ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose

monitoring systems for self-testing in managing diabetes mellitus.
- CLSI EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition.

L. Test Principle:

The GenStrip test strip is based on electrochemical methodologies. The system quantitatively measures blood glucose levels using an amperometric method. The system employs glucose oxidase and flavin adenine dinucleotide enzyme chemistry. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen and the signal is converted into a readout displayed on the meter.

M. Performance Characteristics (if/when applicable):

The sponsor states that the following performance evaluation provided for the GenStrip test strips was obtained using the 3 claimed meters (LifeScan OneTouch Ultra, OneTouch Ultra 2, and OneTouch UltraMini) purchased before July 2010. The sponsor states that three GenStrip test strip calibration codes (10, 13, and 4) were used in each of the performance evaluations.

1. Analytical performance:

   a. Precision/Reproducibility:
   The sponsor evaluated between-day precision using GenStrip test strips with 10 of each of the meters, the OneTouch Ultra, OneTouch Ultra 2, and OneTouch UltraMini meters. Three levels of control solutions were tested in replicates of 10 over ten consecutive days on using for a total of 100 tests per glucose level per meter type. Results are summarized below.

Between-day precision for glucose:

Control Solution	Meter	Average (mg/dL)	CV (%)
Level 1	Ultra	40.3	4.4%
	Ultra2	40.1	4.2%
	UltraMini	40.8	4.2%
Level 2	Ultra	117.6	2.5%
	Ultra2	118.3	2.4%
	UltraMini	118.0	2.5%
Level 3	Ultra	454.1	2.5%
	Ultra2	453.3	2.4%
	UltraMini	453.7	2.4%

The sponsor performed within-run precision studies using venous whole blood adjusted to 6 different glucose concentrations (approximately 42, 84, 134, 233, 384, 494 mg/dL). Each glucose level was analyzed in replicates of 10 with GenStrip test strips and ten (10) each of the OneTouch Ultra, Ultra 2, and UltraMini meters for a total of 100 tests per each glucose level for each meter type. Results are summarized below:

Within-run precision for glucose:

Ultra			Ultra2			UltraMini	
Average Glucose (mg/dL)	CV (%)		Average Glucose (mg/dL)	CV (%)		Average Glucose (mg/dL)	CV (%)
42	3.3		42	3.0		42	3.3
84	1.9		85	1.8		84	1.9
134	2.0		135	2.2		134	2.2
233	1.7		233	1.8		233	1.8
385	1.8		384	1.7		384	1.6
492	2.2		493	2.2		494	2.1

b. Linearity/assay reportable range:

Linearity was evaluated using three test strip lots and 9 mixed pools of venous blood samples with glucose concentrations of 20, 47-48, 105, 202, 304-311, 398-405, 495-510, 540-545, 597-600 mg/dL (as measured by YSI). Each level was measured in replicates of 10 with each of 3 test strip lots and each meter type (Ultra mini, Ultra, and Ultra2) the results from the GenStrip and each of the meters were compared with those obtained from YSI-2300. Results from regression analysis:

Results from the GenStrip test strips and the Ultra meter:

Test strip lot #1: $y = 0.98x + 2.9$; $R^2 = 0.99$
Test strip lot #2: $y = 0.98x + 2.9$; $R^2 = 0.99$
Test strip lot #3: $y = 0.99x + 2.6$; $R^2 = 0.99$

Results from the GenStrip test strips and the Ultra2 meter:

Test strip lot #1: $y = 0.99x + 1.6$; $R^2 = 0.99$
Test strip lot #2: $y = 0.98x + 2.4$; $R^2 = 0.99$
Test strip lot #3: $y = 0.99x + 0.9$; $R^2 = 0.99$

Results from the GenStrip test strips and the UltraMini meter:

Test strip lot #1: $y = 0.99x - 3.1$; $R^2 = 0.99$
Test strip lot #2: $y = 0.98x - 2.8$; $R^2 = 0.99$

Test strip lot #3: $y = 0.97x - 2.1$; $R^2 = 0.99$

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 capillary glucose values obtained with the GenStrips were compared to the YSI method. See the method comparison in 2.a. below.

There are two commercially available control solutions available for use with GenStrip test strips: LifeScan Ultra control solution (targeted at 120 mg/dL glucose) and the Streck Sugar-Chex II Elevated (targeted at 480 mg/dL glucose). The GenStrip test strip insert instructs the user to use these control solutions and the expected control ranges are printed on the GenStrip test strip vial labels.

Three of each meter type (Ultra, Ultra2, and UltraMini) were used to evaluate whether GenStrip test strips responded to control solution appropriately. The control solution range assignment indicated on GenStrip test strips bottle labels is based on mean ± 2.5 times the standard deviation.

Testing protocols and acceptance criteria for the GenStrip test strips shelf-life and open vial stabiltiy were provided. The manufacturer claims shelf life stability of 18 months and an open-vial stability of 3 months at the recommended storage temperatures of 40°F-86°F.

d. Detection limit:

See linearity study in Section M1b above.

e. Analytical specificity:

Interference studies were performed using the GenStrip test strips and the three meter types (OneTouch Ultra, Ultra2 and UltraMini) by spiking venous blood with two levels of glucose concentrations (30, 100 and 400 mg/dL) and the potential interferents. Each test sample was tested in replicates of 5 and the % difference between the interferent containing sample and the control sample calculated. The sponsor defines no significant interference as ≤+/-10 mg/dL for glucose values ≤75 mg/dL and ≤+/-10% for glucose values >75 mg/dL difference relative to the control sample. Results are presented in the table below:

Potential Interfering Substance	Concentration with no Significant Interference (mg/dL)		Potential Interfering Substance	Concentration with no Significant Interference (mg/dL)
Acetaminophen	7.5		L-Dopa	3
Ascorbic Acid	6		Salicyate	50
Bilirubin	15		Tolbutamide	25
Cholesterol	758		Tolazamide	25
Gentistic acid	7.5		Triglycerides	3000
Ibuprofen	40		Uric Acid	5

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

➢Interferences: Abnormally high concentrations of L-dopa, ascorbic acid, acetaminophen, uric acid and gentistic acid may cause falsely high results.

For nominal glucose levels of 30 mg/dL interferences occur for Ldopa at concentrations of >3.0 mg/dL in all three meters claimed; for acetaminophen at concentrations >7.5 mg/dL in all three meters claimed; for uric acid at concentrations >5.0 mg/dL in all three meters claimed; and for gentisic acid at concentrations >7.5 mg/dL in all three meters claimed. Levels seen in normal blood or with normal therapeutic concentrations do not significantly affect results.

➢Lipemic samples: Cholesterol levels up to 758 mg/dL and triglycerides up to 3000 mg/dL do not affect results. Grossly lipemic samples have not been evaluated. Do not test such samples with these test strips.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

System Accuracy:

To assess system accuracy in the hands of lay-user participants, results from the GenStrip test strip and the OneTouch Ultra, Ultra2 and UltraMini meters were compared to a reference method, YSI 2300D Glucose Analyzer. Results were analyzed by comparing blood glucose results from the GenStrip test strip obtained by lay-users with capillary samples from fingerstick, forearm and palm to the YSI results. The samples used in the study ranged from 59-521 mg/dL as measured by YSI. The results relative to YSI are summarized in the tables below:

GenStrip test strips with OneTouch Ultra meter:

For glucose concentrations <75 mg/dL

	within ± 5 mg/dL	Within ± 10 mg/dL	within ± 15 mg/dL
Finger	7/8 (88%)	8/8 (100%)	8/8 (100%)
Palm	3/5 (60%)	5/5 (100%)	5/5 (100%)
Forearm	5/5 (100%)	5/5 (100%)	5/5 (100%)

For glucose concentrations ≥ 75 mg/dL

	Within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
Finger	120/296 (41%)	218/296 (74%)	276/296 (93%)	294/296 (99%)
Palm	120/222 (54%)	181/222 (82%)	207/222 (93%)	218/222 (98%)
Forearm	95/222 (43%)	168/222 (76%)	211/222 (95%)	221/222 (99.5%)

GenStrip test strips with OneTouch Ultra2 meter:

For glucose concentrations <75 mg/dL

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Finger	6/8 (75%)	8/8 (100%)	8/8 (100%)
Palm	7/8 (88%)	8/8 (100%)	8/8 (100%)
Forearm	5/7 (71%)	7/7 (100%)	7/7 (100%)

For glucose concentrations ≥ 75 mg/dL

	Within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
Finger	135/296 (46%)	229/296 (77%)	281/296 (95%)	293/296 (99%)
Palm	121/221 (55%)	183/221 (83%)	209/221 (95%)	220/221 (99.5%)
Forearm	160/222 (48%)	172/222 (77%)	209/222 (94%)	220/222 (99%)

GenStrip test strips with OneTouch UltraMini meter:

For glucose concentrations <75 mg/dL

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Finger	19/12 (75%)	12/12 (100%)	12/12 (100%)
Palm	5/8 (63%)	8/8 (100%)	8/8 (100%)
Forearm	8/8 (100%)	8/8 (100%)	8/8 (100%)

For glucose concentrations ≥ 75 mg/dL

	Within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
Finger	204/444 (46%)	341/444 (77%)	416/444 (94%)	441/444 (99%)
Palm	147/296 (50%)	248/296 (84%)	284/296 (96%)	293/296 (99%)
Forearm	123/296 (42%)	211/296 (71%)	280/296 (95%)	295/296 (99.6%)

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):

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Expected glucose values for people without diabetes:

	Range
Before meals	70-130 mg/dL
Two hours after meals	<180 mg/dL

American Diabetes Association Standards of Medical Care in Diabetes – 2012, Diabetes Care Vol. 35; Suppl. 1:S11-S63).

N. Proposed Labeling:

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

O. Conclusion:

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