

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

A. 510(k) Number:

k062555

B. Purpose for Submission:

Clearance of a new device.

C. Measurand:

Glucose

D. Type of Test:

Blood Glucose Concentration through a Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:

Visgeneer, Inc.

F. Proprietary and Established Names:

eBsensor Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1345, Glucose Test System
21 CFR § 862.1660, Single (specified) analyte controls (assayed and unassayed)
2. Classification:
Class II
Class I (reserved)
3. Product code:
NBW, CGA, JJX
4. Panel:
75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
See Indications for use.
2. Indication(s) for use:
The eBsensor Blood Glucose Monitoring System, eB-G is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by person with diabetes, or in clinical setting by health care professionals, as an aid to monitor the effectiveness of diabetes control.
3. Special conditions for use statement(s):
For Over-the-Counter use.
4. Special instrument requirements:
eBsensor Blood Glucose Monitoring System

I. Device Description:

The eBsensor Blood Glucose Monitoring System is based on an electrochemical biosensor technology and the principle of capillary action. Capillary action at the end of the test strip

draws the blood into the action chamber and your blood glucose result is displayed in 10 seconds. The control solutions available are used to test the performance of the device.

J. Substantial Equivalence Information:

1. Predicate device name(s):
LifeScan, Inc. One Touch Ultra Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
k043197
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase

Differences		
Item	Device	Predicate
Sample Source	The glucose concentration is measured with capillary whole blood from the fingertip.	The glucose concentration is measured with quantitative capillary whole blood from the fingertip and forearm.
Test Range	30 – 600 mg/dL	20 – 600 mg/dL
Volume Required	2.5 µL	1.0 µL
Test Time	10 seconds	5 seconds

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

L. Test Principle:

Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip’s electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, and the current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
The sponsor evaluated the precision of the device using replicate measurements of glucose adjusted venous whole blood. Ten samples at 5 different concentrations were tested on ten meters each tested with 3 strip lots. Results are summarized below.

Lot	Level 1 (30-50 mg/dL)			Level 2 (51-110 mg/dL)			Level 3 (111-150 mg/mL)		
	Average	SD	%CV	Average	SD	%CV	Average	SD	%CV
1	42.03	3.10	7.38	81.59	3.28	4.02	135.1	6.00	4.44
2	41.72	2.62	6.27	81.62	3.39	4.15	135.4	6.21	4.59
3	41.48	2.41	5.81	81.43	3.21	3.95	135.06	5.91	4.37

Lot	Level 4 (151-250 mg/mL)			Level 5 (250-400 mg/mL)		
	Average	SD	%CV	Average	SD	%CV
1	228.11	10.79	4.73	331.87	13.98	4.21
2	220.55	9.69	4.39	329.78	13.20	4.00
3	219.4	9.21	4.20	330.24	13.81	4.18

The sponsor also evaluated the precision of the device using replicate measurements of glucose controls. Three different concentrations using the same lot of control solutions were tested on ten meters each tested once per day for 10 days with 6 strip lots. Results are summarized below.

Lot	Level 1 (30-50 mg/dL)			Level 2 (96-144 mg/dL)			Level 3 (280-420 mg/mL)		
	Average	SD	%CV	Average	SD	%CV	Average	SD	%CV
1	52.5	2.55	4.86	102.9	4.92	4.78	313.8	7.93	2.53
2	52.3	2.72	5.19	103.8	3.98	3.83	315.0	6.95	2.21
3	51.1	2.48	4.85	102.5	4.17	4.07	314.2	10.56	3.36
4	51.7	2.39	4.62	104.4	3.69	3.53	316.4	7.14	2.26
5	52.2	2.38	4.55	105.0	3.92	3.74	315.2	6.78	2.15
6	52.8	2.78	5.26	103.0	4.19	4.07	313.4	7.48	2.39

b. Linearity/assay reportable range:

To establish the linearity of the eSensor system through the range of 30 to 400 mg/dL glucose adjusted whole blood samples were compared to YSI 2300. Linear regression yields the following statistics:

N	30
Slope	0.957
y-intercept	6.116
r ²	0.994

A study with a range of 50 to 550 mg/dL was also performed. Glucose adjusted whole blood samples were compared to YSI 2300. Linear regression yields the following statistics:

N	30
Slope	0.997
y-intercept	-0.673
r ²	0.995

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
 The device is traceable to a laboratory analyzer which is calibrated to a glucose standard (NIST SRM 965a).

Stability characteristics of the two control solutions were determined using real-time stability studies to determine the storage stability at room temperature (24±3°C) to be 18 months.

The expected values for the two glucose control solutions were established by repeat testing (10 times) on ten meters using three lots of strips for both glucose levels. The expected results may change with each new lot, but the control range is listed in the product insert.

- d. *Detection limit:*
 The measuring range of the eBSensor Blood Glucose Monitoring System is 30 - 600 mg/dL. This range was validated via the linearity study (above).
- e. *Analytical specificity:*
 The sponsor tested the following substances for interference. The following results were determined with regard to interfering substances:

Substance	No Interference
Acetaminophen	< 1.25 mg/dL
L-Dopa	< 1 mg/dL
Dopamine	< 1 mg/dL
Methyl-Dopa	< 3 mg/dL
Glibenclimide	< 1 mg/dL
Ascorbic Acid	< 1.25 mg/dL
Creatinine	< 1.25 mg/dL
Uric acid	< 10 mg/dL
Bilirubin	< 1.85 mg/dL

An altitude study was performed with 20 volunteers' whole blood samples and 5 different concentrations of glucose spiked whole blood spanning 88 to 353 mg/dL. The volunteers test results and the spiked whole blood samples were measured by the

eBsensor. The volunteer samples were compared to YSI and found to be acceptable (within Zone A using EGA with a linear regression of $y=0.9278x+8.3196$ with an $r^2=0.9618$. With the spiked samples, a repeatability study was performed with a single lot of strips and 10 different meters which showed a coefficient of variation lower $<5\%$ for each concentration. The altitude study was performed at 10,744 feet; however the sponsor will make the claim of no effect on blood glucose measurements of up to 8000 feet.

Additionally the sponsor performed a temperature study verifying the operational limits of the meter fall with-in $5^{\circ}\text{C} \sim 42^{\circ}\text{C}$ ($41^{\circ}\text{F} \sim 107.6^{\circ}\text{F}$)

f. *Assay cut-off:*
Not Applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor demonstrated that the eBsensor Blood Glucose Monitoring System for finger stick is equivalent to two standard methods (YSI-2300 and Hitachi) by having 179 patient samples with a hematocrit range of 30-55% test their blood as well as a technician. Samples ranged from 53 to 449 mg/dL (according to YSI). The studies are summarized below:

	YSI vs. Patient Finger	YSI vs. Technician Finger	Hitachi vs. Patient Finger	Hitachi vs. Technician Finger
N	179	179	179	179
Slope	0.9627	0.9644	0.8701	0.8691
Intercept	6.7839	5.7646	17.156	18.063
r^2	0.9637	0.9729	0.9562	0.9484

b. *Matrix comparison:*

See above: *Method comparison with predicate device*

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):*

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

The sponsor included the following Expected Values for normal glucose levels in their strip labeling:

Status	Range (mg/dL)	Range (mmol/L)
Before meals	70-110	3.9-6.1
2 hours after meals	<120	<6.7

Source: Tietz, N.W., Textbook of Clinical Chemistry, p.2190, (1994).

N. Instrument Name:

eBsensor Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings.

2. Software:

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

Yes or 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:

This device is intended to be used with capillary whole blood from the finger, only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

A calibration card is provided with each batch of test strips to calibrate the meter for that batch. No further calibrations are required of the user.

6. Quality Control:

The sponsor is providing a high and low glucose control solution with this device. When a test strip is inserted into the meter, a control can be run. An acceptable range for each control level is printed on the test strip vial label. The user is referred to the troubleshooting section of the owner's manual if control results fall outside these ranges.

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

None.

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.