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

A. 510(k) Number:

k091765

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative amperometric assay, glucose oxidase

E. Applicant:

Visgeneer, Inc

F. Proprietary and Established Names:

eB*carryon* Blood Glucose Monitoring System

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. Indications(s) for use:
   The eB*carryon* Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger. The eB*carryon* Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus and is not for use on neonates. 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):
   Not intended for use on neonates
   Not for the diagnosis of or screening for diabetes mellitus
   Not to be used for patients who are dehydrated, hypotensive or in shock
   Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
   Not for use on critically ill patients
   Not for use on samples obtained from sites other than the fingertip

4. Special instrument requirements:
   eB*carryon* Blood Glucose Monitoring System

I. Device Description:

The eBcarryon Blood Glucose Monitoring System contains the blood glucose meter, lancing device, lancets, normal and high control solutions, test strips, check card, and User's Manual.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   eBsensor Blood Glucose Monitoring System, eB-G

2. Predicate 510(k) number(s):
   k062555

3. Comparison with predicate:

Similarities		
Item	Device (eB*carryon*)	Predicate (k062555)
Indications for use	The eB*carryon* Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger. The eB*carryon* Blood Glucose Monitoring System is not intended for the diagnosis of ro screening for diabetes mellitus and is not for use on neonates. 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	Same
Test Principle	Electrochemical biosensor with carbon	Same

Similarities		
Item	Device (eB*carryon*)	Predicate (k062555)
	electrodes that measures current produced by a chemical reaction	
Enzyme	Glucose oxidase	Same
Sample Type	Fresh capillary whole blood	Same
Sample Site	Fingertip	Same
Sample volume	2.5 μL	Same
Measuring time	10 sec	Same
Measurement range	30-600 mg/dL	Same

Differences		
Item	Device	Predicate (k073118)
Meter dimensions (mm)	110x58x25 mm in manual	87x60x21 mm
Weight (g)	63 g	75 g
Memory Storage	2 blood glucose results	70 blood glucose results

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

- ISO15197:2003- *In vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- IEC/EN 60601-1: Medical electrical equipment Part 1. General requirements for safety, 2001.

L. Test Principle:

The eBcarryon Blood Glucose Monitoring System is based on an electrochemical biosensor technology and the principle of capillary action. The glucose in the sample is oxidized by the enzyme glucose oxidase, and the magnitude of the resulting electrical current generated, which is proportional to the concentration of glucose in the specimen, is converted into a readout that is displayed on the meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor performed precision studies in accordance with the ISO 15197 guideline. Adjusted venous whole blood samples at 5 glucose levels (hematocrit range 35 to 50%) were used for within-day precision studies. Each concentration was tested 10 times each on 10 meters, each with 3 test strip lots, for a total of 300 tests per blood glucose level. The reference value was determined by the YSI 2300 glucose analyzer. Results are summarized below:

	Level 1 (30-50 mg/dL)			Level 2 (51-110 mg/dL)			Level 3 (111-150 mg/dL)		
Lot	**Average**	**SD**	**%CV**	**Average**	**SD**	**%CV**	**Average**	**SD**	**%CV**
1	45.12	3.54	7.85	94.24	3.26	3.46	133.78	4.35	3.25
2	45.63	3.62	7.94	92.64	3.43	3.70	133.34	4.66	3.50
3	44.7	3.56	7.97	94.22	3.28	3.48	133.08	4.56	3.43

	Level 4 (151-250 mg/dL)			Level 5 (250-400 mg/dL)		
Lot	**Average**	**SD**	**%CV**	**Average**	**SD**	**%CV**
1	201.49	6.67	3.31	311.01	10.64	3.42
2	200.78	7.4	3.68	310.64	11.14	3.59
3	201.52	7.44	3.69	312.66	10.20	3.26

The sponsor also evaluated the day-to-day precision of the device using replicate measurements of glucose control solutions (low, normal, and high). Three different concentrations, using the same lot of control solutions, were tested on 10 meters, each tested once per day for 10 days with 3 strip lots, for a total of 300 tests per blood glucose level. Results are summarized below.

	Level 1 (30-50 mg/dL)			Level 2 (96-144 mg/dL)			Level 3 (280-420 mg/dL)		
Lot	**Average**	**SD**	**%CV**	**Average**	**SD**	**%CV**	**Average**	**SD**	**%CV**
1	41.7	3.43	8.23	131.6	4.87	3.70	372.4	9.25	2.48
2	42.8	3.62	8.46	133.9	4.75	3.54	371.5	11.18	3.01
3	40.8	3.6	8.82	132.5	4.47	3.38	371.5	11.39	3.07

b. Linearity/assay reportable range:

The sponsor performed linearity studies using adjusted whole blood samples with 10 different glucose concentration ranges from 21 to 647 mg/dL. Each sample was tested 60 times with the eBcarryon System and the results compared to those obtained using YSI 2300. The results demonstrate less than ± 9 mg/dL difference for samples with glucose concentrations <75 mg/dL and less than 8% bias for those >75 mg/dL glucose. Linear regression analysis resulted in: $y = 0.9859x - 1.6836$; $r^2 = 0.996$.

The claimed reportable range of the device is 30 to 600 mg/dL.

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).

The eBsensor control solutions, normal (100 mg/dL) and high (300 mg/dL) were previously cleared in k062555.

c. Detection limit:

The measuring range of the device is 30-600 mg/dL. This range was validated via the linearity study (see section M.1.b.).

d. Analytical specificity:

The sponsor performed interference studies with spiked venous blood samples at five concentrations of glucose (30 to 50, 51 to 110, 111 to 150, 150 to 250, and 251 to 400 mg/dL) that were prepared and divided into a test pool and a control pool. The potential interferents listed in the table below were added to the sample and each sample was analyzed 20 times. The sponsor defines interference as a change in glucose value relative to the control of greater >10%. Interference was observed for L-Dopa at concentrations ≥1.25 mg/dL and for Dopamine at concentrations ≥ 3 mg/dL. The sponsor states in the labeling that therapeutic concentrations of L-dopa and dopamine may affect test results. The table below list the substances tested and the concentrations at which no significant interference was observed:

Substance	**Concentration at which no Interference was observed**
Acetominophen	< 10 mg/dL
L-Dopa	< 1.1 mg/dL
Tolbutamide	< 100 mg/dL
Dopamine	< 2 mg/dL
Ibuprofen	< 20 mg/dL
Salicylic acid	< 50 mg/dL
Methy-Dopa	< 3 mg/dL
Tetracycline	< 10 mg/dL
Glibenclimide	< 1 mg/dL
Ketoprofen	< 20 mg/dL
Diclofenac	< 20 mg/dL
Indomethacin	< 20 mg/dL
Amiloride	< 20 mg/dL
Colchicine	< 20 mg/dL
Atenolol	< 20 mg/dL
Ascorbic Acid	< 3 mg/dL
Creatinine	< 5 mg/dL
Uric acid	< 15 mg/dL
Cholesterol	< 500 mg/dL
Bilirubin	< 10 mg/dL
Triglyceride	< 3000 mg/dL

Hematocrit Study:

The effect of different hematocrit levels on the accuracy of the device was evaluated on the eB*carryon* Blood Glucose Monitoring System with 5 meters. Blood samples at 8 hematocrit levels from 25% to 60% (25, 30, 35, 40, 45, 50, 55, and 60) were adjusted to 9 concentrations of glucose (28, 66, 105, 148, 260, 372, 476, 581, 663 mg/dL). In total, 40 measurements were made at each of the glucose levels and the bias was calculated relative to the YSI values and to the glucose values at 40% hematocrit. The results support the claims for use with hematocrit of 30 to 55% with

biases due to hematocrit that did not exceed ±15 mg/dL for glucose values <75 mg/dL or 15% for glucose values ≥75 mg/dL.

Altitude study:
An altitude study was performed at 8125 feet with 50 tests each of 5 different concentrations of glucose spiked whole blood spanning 22 to 661 mg/dL (22, 33, 289, 575, and 661 mg/dL). The eBcarryon Blood Glucose Monitoring System results were compared to YSI values and resulted in a % bias < 9% for all samples tested with glucose >75 mg/dL and no greater than ±8 mg/dL for samples with <75 mg/dL glucose. The results support the claims that altitudes up to 8000 ft have no significant effect on eBcarryon blood glucose measurements.

Temperature and humidity studies:
The sponsor performed temperature and humidity studies that demonstrated that the eBcarryon Blood Glucose Monitoring System can be used at temperatures of 10 to 40°C and at a relative humidity <85%, and stored at temperatures of 0 to 50°C and at a relative humidity <95%.

e. Assay cut-off:
Not Applicable

2. Comparison studies:
   a. Method comparison with predicate device:

System Accuracy:
The sponsor performed an accuracy study to demonstrate that the eBcarryon Blood Glucose Monitoring System is equivalent to the predicate (eBsensor) and YSI 2300. Fingerstick samples, with glucose values of 43 to 452 mg/dL, were collected by a technician from 100 subjects (with hematocrit of 30 to 55%). Results were obtained by a technician using the eBcarryon meter and the eBsensor meter (predicate) and were compared to the values obtained from YSI.

System Accuracy Evaluation (eBcarryon vs YSI):
For glucose concentrations <75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
19/26 (73.1%)	26/26 (100%)	26/26 (100%)

For glucose concentrations ≥ 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
121/174 (69.5%)	163/174 (93.7%)	174/174 (100%)	174/174 (100%)

The following results were obtained from linear regression analysis:

Comparison	N	Slope and y-intercept	R^2
eBcarryon vs. YSI	100	y = 1.058x + 0.4929	0.997

User Performance Study:
The sponsor performed a user study with 150 lay user participants and one technician to demonstrate the accuracy of the eBcarryon system. Participants, who were able to read the User's Manual in English, were instructed to read the manual and perform testing on the finger. The technician then performed the test on a finger stick sample from the user. The samples ranged from 71 to 463 mg/dL glucose (30-55% hematocrit). Results are summarized below.

Lay-user vs. YSI:

For glucose concentrations ≤75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
1/3 (33%)	3/3 (100%)	3/3 (100%)

For glucose concentrations >75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
109/147 (74.8%)	143/147 (97.3%)	147/147 (100%)	147/147 (100%)

Technician vs. YSI:

For glucose concentrations ≤75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
3/3 (33%)	3/3 (100%)	3/3 (100%)

For glucose concentrations >75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
112/147 (76.2%)	142/147 (96.6%)	147/147 (100%)	147/147 (100%)

The following results were obtained from linear regression analysis:

Comparison	N	Slope and y-intercept	R^2
Lay-user vs. YSI	150	y = 1.0089x + 0.6668	0.9857
Technician vs. YSI	150	Y = 1.0054x + 1.3957	0.986

b. Matrix comparison:
Not Applicable, capillary whole blood is the only indicated matrix.

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 glucose values for people without diabetes in the User's Manual and Test Strip insert*:

   Before meals: 70-110 mg/dL (3.9 – 6.1 mmol/L)
   2 hours after meals: Less than 120 mg/dL (6.7 mmol/L)

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

N. Instrument Name:

eB*carryon* 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.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes _____ or No ___X___.

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___X___.

2. Software:

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

   Yes __X___ or No _____

   The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

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, which can be applied directly to the test strip.

5. Calibration:

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

6. Quality Control:

   The sponsor provides a normal control solution with the device. An additional high control solution is available for purchase from the U.S. distributor, CTL Scientific Supply Corp. When a test strip is inserted into the meter, a control solution can be tested. 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:

The sponsor provided a readability study and obtained Flesch-Kincaid Grade Level Scores of no more than 7.5 for the eBcarryon User's Manual, test strip labeling and control solution labeling.

The sponsor stated they conformed to the IEC/EN 60601-1: Medical electrical equipment Part 1. General requirements for safety, 2001 guideline and provided the appropriate documentation demonstrating compliance.

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.