

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

**A. 510(k) Number:**

k122181

**B. Purpose for Submission:**

New device

**C. Measurand:**

Capillary whole blood glucose from the finger

**D. Type of Test:**

Quantitative amperometric (glucose oxidase)

**E. Applicant:**

Visgeneer Inc.

**F. Proprietary and Established Names:**

*eBchek* Blood Glucose Monitoring System

**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, Quality Control Material

4. Panel:

Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

The *eBchek* Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The *eBchek* Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The *eBchek* Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The *eBchek* Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes mellitus or for neonatal use. The *eBchek* Glucose Meter contains some speaking functions, but is not intended for use by the visually impaired.

*eBchek* Blood Glucose Test Strips are for use with the *eBchek* Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

*eB-series* Control Solutions are for use with the *eBchek* Blood Glucose Meter and *eBchek* Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

3. Special conditions for use statement(s):

- For in vitro diagnostic use only
- For over-the-counter use
- For single-person use only.
- Not intended for use on neonates
- Not for the diagnosis of or screening for diabetes mellitus
- Not for use on patients who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with a blood glucose meter.
- Not intended for alternative site testing

4. Special instrument requirements:

## **eBchek** Blood Glucose Meter

### **I. Device Description:**

The eBchek Blood Glucose Monitoring System consists of the eBchek Blood Glucose Meter, eBchek Blood Glucose Test Strips, Lancing device, Lancets, Code card, two AAA Batteries, User's Manual, and Carrying Case. eB-series Control Solutions (Level 1 and Level 2 are available but sold separately).

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

The eB-series Control Solutions contain a known amount of glucose that reacts with eBchek Test Strips. Two different concentrations of eB-series control solutions, Level 1 and Level 2, are used to check if the meter and test strips are working together properly and that users are performing the test correctly. The test result using control solution should fall within an expected range of results printed on the vial of test strips.

The eBchek Blood Glucose Meter has a speaker function but is not intended for use by the visually impaired.

### **J. Substantial Equivalence Information:**

1. Predicate device name(s):

Visgeneer eBsensor Blood Glucose Monitoring System (Model: eB-G)

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

k062555

3. Comparison with predicate:

<b>Item</b>	<b>Candidate Device eB<i>chek</i> Blood Glucose Monitoring System</b>	<b>Predicate Device (k062555) eBsensor (eB-G) Blood Glucose Monitoring System</b>
<b>Similarities</b>		
Intended Use	Same	The System is used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips. It is used by people with diabetes, as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of or screening for diabetes mellitus and is not for use on neonates. Testing is for in vitro diagnostic use only.
Test Principle	Same	Electrochemical biosensor with carbon electrodes
Specimen Type	Same	Capillary whole blood
Measurement unit	Same	mg/dL or mmol/L
Enzyme	Same	Glucose oxidase
Control Solution	Same	eB-series control solution (D-glucose, two different concentrations at 100 and 300 mg/dL)

Calibration	Same	Code card required for each lot of test strips
Strip Dimension	Same	7.9 mm x32 mm
<b>Item</b>	<b>Candidate Device eBchek (eB-S01) Blood Glucose Monitoring System</b>	<b>Predicate Device (k062555) eBsensor (eB-G) Blood Glucose Monitoring System</b>
<b>Similarities (cont)</b>		
Data Output	RS232 PC Interface	Same
Battery Power	Two 1.5 V AAA batteries	Same
Operating Temperature Range	50 - 104° F (10 - 40° C)	Same
Operating Humidity Range	10 - 85% RH	Same
<b>Item</b>	<b>Candidate Device eBchek (eB-S01) Blood Glucose Monitoring System</b>	<b>Predicate Device (k062555) eBsensor (eB-G) Blood Glucose Monitoring System</b>
<b>Differences</b>		
Intended use	Single patient	Single patient and Healthcare Professionals
Sample Volume	0.5 uL	2.5 uL
Measuring Time	5 seconds	10 seconds
Hematocrit Range	20 - 60%	30 - 55%
Measuring Range	20 - 600 mg/dL (1.1 - 33.3 mmol/L)	30 - 600 mg/dL (1.6 - 33.3 mmol/L)

Slot location	Bottom	Top
Glucose Average	7, 14 and 28 days	None
Memory Storage	450 blood glucose result	70 blood glucose results
Speaking Function	English/Chinese	None
Meter Dimensions	95 mm x 55 mm x 18.5 mm	87 mm x 60 mm x 21 mm
Meter Weight	85 g	75 g

**K. Standard/Guidance Document Referenced:**

- EN 61326-1:2006: Electrical equipment for measurement, control, and lab use. EMC requirements: General requirements
- EN 61326-2:2006: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-3: Particular requirements - Test configuration, operational conditions and performance criteria for transducers with integrated or remote signal conditioning"
- EN 61010-1:2001 Safety requirements for electrical equipment for measurement, control and lab use - Part 1: General requirements
- ISO 15197:2003: In Vitro Diagnostic Test Systems—Requirements for Blood Glucose Test Systems for Self Managing Diabetes Mellitus.

**L. Test Principle:**

The *eBcheck* Blood Glucose Monitoring System uses electrochemical methodologies to quantitatively measure blood glucose levels by amperometry. The device detects the current produced from oxidation of blood glucose by the enzyme glucose oxidase impregnated in the test strip. 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):**

1. Analytical performance:

a. *Precision/Reproducibility:*

The repeatability study was performed with three test strip lots and 10 meters using venous blood samples spiked to five different concentrations that covered the measuring range of the device. Each sample was tested 10 times for a total n of 150 (5 concentrations x 10 replicates x 3 strip lots). The final glucose concentrations for the blood samples were confirmed by YSI. The blood samples had hematocrit levels of 35 - 50%. Results are summarized below:

**Within Day Precision:**

Lot 1

Level/Ranges (mg/dL)	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Level 1 (30-50)	100	46.8	2.58	5.51
Level 2 (51-110)	100	102.3	3.98	3.89
Level 3 (111-150)	100	143.5	4.64	3.24
Level 4 (151-250)	100	223.6	7.02	3.14
Level 5 (251-400)	100	351.7	11.0	3.13

Lot 2

Level/Ranges (mg/dL)	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Level 1 (30-50)	100	47.0	2.38	5.08
Level 2 (51-110)	100	102.1	3.39	3.32
Level 3 (111-150)	100	142.4	4.64	3.26
Level 4 (151-250)	100	223.3	7.80	3.49
Level 5 (251-400)	100	352.5	12.4	3.52

Lot 3

Level/Ranges (mg/dL)	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Level 1 (30-50)	100	47.0	2.57	5.47
Level 2 (51-110)	100	102.4	3.55	3.47
Level 3 (111-150)	100	143.3	4.80	3.35
Level 4 (151-250)	100	222.6	8.49	3.81
Level 5 (251-400)	100	352.4	11.1	3.15

Intermediate precision studies were performed with three test strip lots and 10 meters analyzing 3 glucose control solutions for a 10 day period. The test samples had hematocrit levels of 30%-50%. Results are

summarized below:

### Intermediate precision

#### Lot 1

Level/Ranges (mg/dL)	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Level 1 (30-50)	100	44.2	2.58	5.85
Level 2 (96-144)	100	133.0	4.51	3.39
Level 3 (280-420)	100	365.3	7.20	1.97

#### Lot 2

Level/Ranges (mg/dL)	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Level 1 (30-50)	100	43.8	2.88	6.57
Level 2 (96-144)	100	133.9	4.75	3.54
Level 3 (280-420)	100	362.1	8.95	2.47

#### Lot 3

Level/Ranges (mg/dL)	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Level 1 (30-50)	100	45.0	2.74	6.09
Level 2 (96-144)	100	133.9	3.87	2.89
Level 3 (280-420)	100	362.8	9.38	2.58

*b. Linearity/assay reportable range:*

Linearity was evaluated using venous whole blood samples spiked with 10 different concentrations of glucose ranging in concentration from 14 - 633 mg/dL, as measured by the YSI reference method. The blood samples had hematocrit levels of 35 - 50%. The data was collected in singlicate with ten meters over six runs (n = 60 for each concentration). Results are summarized below:

Slope	Intercept	R <sup>2</sup>
1.0162	4.6032	0.9986

The study results support the sponsor's claimed glucose measurement range of 20 - 600 mg/dL.

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

## **Traceability**

This assay is traceable to the YSI method and NIST material SRM965.

### **Stability - *eB-series Controls*:**

Stability for the *eB-series Controls* was established when the controls were previously cleared under k062555 with the name eBsensor Control Solutions.

### **Stability – *eBchek Glucose Test Strips***

Opened vial test strip stability was evaluated in real-time and accelerated studies. Protocols and acceptance criteria were reviewed and found to be acceptable. The data from these studies supports the claimed open vial stability of 90 days when stored at 4-30°C and 10 – 85% relative humidity

Real time studies to evaluate the shelf life (closed-vial) stability of the test strips were conducted. Protocols and acceptance criteria were reviewed and found to be acceptable. The data from these studies supports the claimed closed vial stability of two years when stored 4-30°C and 10 – 85% relative humidity.

This information is provided in the labeling of the test strips and control materials.

#### *d. Detection limit:*

The measuring range of the device is 20 - 600 mg/dL. This range was validated by the linearity study (M.1.b).

#### *e. Analytical specificity:*

Interference studies for endogenous and exogenous studies were conducted on 10 *eBchek* meters, with three lots of test strips using venous blood samples. Five glucose concentrations covering the measuring range of the device were analyzed. Potential interference was evaluated for 25 common endogenous and exogenous potential interferents at two concentrations (low and high) as recommended in CLSI EP7-A guideline. Significant interference is defined as a bias  $\geq \pm 10\%$  from the control group as measured by the reference method.

The sponsor claims no significant interference from the following substances at the concentrations shown in the table below:

<b>Interferent</b>	<b>Concentration with &lt;10% interference (mg/dL)</b>
Acetaminophen	13
Tolbutamide	64
Dopamine	0.07
Ibuprofen	50
Salicylic acid	60
Tetracycline	1.5
Ketoprofen	20
Diclofenac	5
Indomethacin	3.6
Amiloride	0.6
Colchicine	20
Atenolol	1
Creatinine	10.0
Cholesterol	500
Triglyceride	3000
L-Dopa	3
Methyl-Dopa	1.4
Maltose	100
Galactose	100
Xylose	200
Tolazamide	10
Ascorbic acid	2.8
Uric acid	15
Bilirubin	10
Hemoglobin	500

In their labeling the sponsor states that abnormally high concentrations of Ascorbic acid, Creatinine, Uric acid, Bilirubin, Acetaminophen, Dopamine, Methyl-Dopa, and other reducing substances may cause inaccurate results.

*f. Assay cut-off:*

Not applicable.

## 2 Comparison studies:

*a. Method comparison with predicate device:*

### **System Accuracy:**

To assess system accuracy, results from the candidate device were compared to the YSI 2300 reference method.. One hundred and two (102) fingerstick capillary blood samples with glucose concentrations ranging from 43to 592 mg/dL were

analyzed by the candidate device and the reference method. One sample was spiked to achieve high glucose levels. The results of linear regression analysis are as follows:

$$y = 0.9988 + 1.20x, r^2 = 0.9969$$

Results from the eBchek Blood Glucose Monitoring System compared to the YSI results are as follows:

System Accuracy Evaluation	< 75 mg/dL		
Strip lot	Within ± 5 mg/dl	Within ±10 mg/dl	Within ± 15mg/dl
1	3/3 (100%)	3/3 (100%)	3/3 (100%)
2	8/8 (100%)	8/8 (100%)	8/8 (100%)
3	4/6 (67%)	6/6 (100%)	6/6 (100%)
Combined	15/17 (88%)	17/17 (100%)	17/17 (100%)

System Accuracy Evaluation	≥ 75 mg/dL			
Strip lot	Within ± 5 %	Within ±10 %	Within ± 15%	Within ± 20%
1	27/29 (93%)	29/29 (100%)	29/29 (100%)	29/29 (100%)
2	30/35 (86%)	35/35 (100%)	35/35 (100%)	35/35 (100%)
3	17/21 (81%)	21/21 (100%)	21/21 (100%)	21/21 (100%)
Combined	74/85 (87%)	85/85 (100%)	85/85 (100%)	85/85 (100%)

*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):*

**User Performance Study:**

A user study was conducted with 150 volunteer lay users who tested his or her own blood samples. The study subjects ranged in age from 33 to 89 years and were about equally divided between males and females. There was a range of educational backgrounds but none had any experience with self-testing for glucose. The only training provided was for the participants to read the User Manual. After reading the User Manual in English only, the subjects performed their own fingerstick without any practice tests and tested their blood glucose using the Visgineer system. Immediately afterwards, a technician collected another fingerstick sample to be tested using the Visgineer system. Finally, a capillary blood sample from the finger was collected and analyzed on the reference analyzer. The samples tested had glucose concentrations ranging from 58 to 451 mg/dL as measured by the reference method. The results of linear regression analysis are as follows:

Lay-users vs. YSI (fingersticks)

Linear regression:  $y = 0.9931x - 1.89$ ,  $r = 0.9966$

Lay-user's results compared to the YSI results:

<b>Samples &lt; 75 mg/dL</b>			
Within ± 5 mg/dl	Within ±10 mg/dl	Within ± 15 mg/dl	
16/16 (100%)	16/16 (100%)	16/16 (100%)	
<b>Samples &gt; 75 mg/dL</b>			
Within ± 5%	Within ±10%	Within ± 15%	Within ± 20%
120/134 (90%)	133/134 (99%)	134/134 (100%)	134/134 (100%)

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Expected blood glucose levels for people without diabetes (referenced from the American Diabetes Association Position Statement, Diabetes Care Vol. 35, Supplement 1, p. S13 (2012).

Time	Range (mg/dL)	Range (mmol/L)
Fasting and before meals	Less than 100 mg/dL	5.6 mmol/L
Two hours after meals	Less than 140 mg/dL	7.8 mmol/dL

**N. Instrument Name:**

*eBchek* Blood Glucose Meter

**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 \_\_\_ No X

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

Yes \_\_\_ No X

2. Software:

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

Yes X 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

The glucose test is intended to be used with capillary whole blood from the fingertips only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

The device must be coded with the code card provided with each vial of test strips. No further calibration is required.

6. Quality Control:

Two levels of glucose control solution (Level 1 and Level 2) are available for the eBcheck Blood Glucose Monitoring System. The meter cannot automatically recognize the control solution, so the user needs to switch to the control mode for a control solution test so the result will not be stored in the meter memory as a blood glucose result. Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. Hematocrit Study:

The effect of different hematocrit levels on the accuracy of the device was evaluated on the eBcheck Blood Glucose Monitoring System with 5 meters and one test strip lot. Blood samples at 8 hematocrit levels from 20% to 60% (20, 30, 35, 40, 45, 50, 55, and 60 %) were adjusted to 8 concentrations of glucose covering approximately 20 to 600 mg/dL. Five replicates were tested for each hematocrit level and glucose concentration. Glucose concentrations were compared to YSI. The study results indicate samples with hematocrit from 20% - 60% do not cause unacceptable bias with glucose concentrations between 20 - 600 mg/dL.

2. Altitude study:

Venous whole blood samples were spiked with glucose to five target ranges: <30, 30 – 50, 50 – 100, 250 – 350, and 500 – 600 mg/dL. Blood glucose target concentrations were verified by the reference YSI glucose analyzer. Glucose measurements were obtained using the eBcheck Blood Glucose Monitoring System at an altitude of 8125 ft. The results demonstrate acceptable bias for samples with glucose concentration  $\geq 35$  mg/dL; the results support the claims in the labeling that altitudes up to 8,000 feet have no significant effect on blood glucose measurements from the eBcheck Blood Glucose Monitoring System.

3. Sample volume study:

A sample volume study was performed to verify the claimed test strip minimum sample volume. Samples were tested at 5 volumes (0.2, 0.3, 0.4, 0.5 and 1.0  $\mu\text{L}$ ) and values obtained were compared to YSI values. Results support the claimed sample volume of 0.5  $\mu\text{L}$ .

4. Temperature and humidity studies:

The sponsor performed studies using venous whole blood samples (glucose concentrations 103, 255, and 552 mg/dL) to evaluate the effect of temperatures ranging from 39 – 108° F (4 - 42° C) and relative humidity from 10% - 90%. Meter results were compared to YSI 2300 reference analyzer. Four temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity. The results support the claims in the labeling that the system can be used in conditions of 10 - 40°C with relative humidity of 10 - 85%

5. Infection Control Studies:

The device is intended for single-patient use. Disinfection efficacy studies were performed using materials that comprise the meter and lancing device by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B (HBV) with Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg No. 56392-8). The sponsor also demonstrated that there was no change in performance or in the external materials of the meter and lancing device up to 260 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 5 years of meter and lancing device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. Electromagnetic Compatibility (EMC) Testing

EMC testing was performed by SGS Taiwan LTD. The testing lab provided a certificate dated Sept 27, 2010 stating that the device met all applicable requirements. Please also see section K above for specific standards related to EMC testing.

7. Flesch-Kincaid readability assessment was conducted and the result show grade level for eBchek user manual, test strip insert and control solution insert were 7.7, 7.4 and 8.1 respectively.

**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.