

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

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

k091914

**B. Purpose for Submission:**

New device

**C. Measurand:**

Quality control materials for blood glucose monitoring system

**D. Type of Test:**

Not applicable

**E. Applicant:**

Bionostics, Inc.

**F. Proprietary and Established Names:**

OMNIS Health Embrace Glucose Control Solution

**G. Regulatory Information:**

1. Regulation section:  
21 CFR § 862.1660 Quality control material (assayed and unassayed)
2. Classification:  
Class I (reserved)
3. Product code:  
JJX, single (specified) analyte controls (assayed and unassayed)
4. Panel:  
Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):  
See indication for use below.
2. Indication(s) for use:  
OMNIS Health Embrace Glucose Control Solution is intended to assess the performance of the OMNIS Health Embrace Blood Glucose test system. OMNIS Health Embrace Glucose Control Solution is intended for use by healthcare professionals and people with diabetes mellitus at home.
3. Special conditions for use statement(s):  
For *in vitro* diagnostic use, over-the-counter use
4. Special instrument requirements:  
For use with the OMNIS Health Embrace Blood Glucose test system.

**I. Device Description:**

OMNIS Health Embrace Glucose Control Solution is a viscosity-adjusted, aqueous liquid glucose control solution. OMNIS Health Embrace Glucose Control Solution is intended for use to verify the performance of the OMNIS Health Embrace Blood Glucose Test System at glucose levels representing normal, fasting blood glucose and elevated glucose levels and is intended for use by healthcare professionals and people with diabetes mellitus at home. The product is packaged in plastic bottles with dropper tips for application of the solution to test strips. The control has a red color to help users see the solution while dispensing onto a test strip.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Omnis Health Embrace Control Solutions
2. Predicate K number(s):  
k090043
3. Comparison with predicate:

Item	Device	Embrace Control Solution (k090043)
<b>Similarities</b>		
Indications for use	Verify performance of a glucose monitoring system	Same
Levels	2 (low and high)	Same
Analyte	Glucose	Same
Target (mg/dL)	114 (low), 229 (high)	Same
Matrix	Aqueous	Same
Color	Red	Same
<b>Differences</b>		
Net Fill	4.0 mL	2.5 mL
Glucose (% w/v)	0.08% (low), 0.15% (high)	0.06% (low), 0.15% (high)
Container	6mL plastic vial	3 mL plastic vial

**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. 1st edition. May 1, 2003
- ISO 14971 – Medical Devices – Application of risk management to medical devices. 1st edition. June 22, 2009
- ISO 13485 – Medical Devices – quality management systems – requirements for regulatory purposes. 2nd edition. July 15, 2003

**L. Test Principle:**

Not applicable

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

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

Value Assignment: A Reference Lot known to conform to the performance specifications for the OMNIS Health Embrace Blood Glucose test system is used to value assign new lots. Each new lot is formulated gravimetrically to be within a specified range of the value of the Reference Lot measured using the YSI 2300 analyzer.

Value assignment verification was performed using at least 2 OMNIS Health Embrace Blood Glucose Meters, 3 lots of OMNIS Health Embrace test strips and 3 lots of the proposed device. Value assignment range is determined as the mean value of all measurements  $\pm 20\%$  of the mean value. Value assignment was verified if at least 95% of all measurements of the new lot of product were within the value assignment ranges printed on the OMNIS Health Embrace Test Strips.

Stability: Stability characteristics of the OMNIS Health Embrace Glucose Control Solution were determined using real-time studies. The product has a closed-vial stability of 24 months when the product is stored at 2 – 30 °C. Open-vial stability is 90 days when the product is stored at 2 – 30 °C, but should not exceed the printed expiration date.

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

Not applicable

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable

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:

The instructions provided to the user are as follow:

“The Embrace Control Solutions testing should provide results within the expected range indicated on the Embrace Test Strip bottle.” Users are instructed to contact customer support if control readings do not fall within the acceptable range after reviewing the procedure and repeating the test.

**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.