

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

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

k103553

**B. Purpose for Submission:**

New device

**C. Measurand:**

Quality control materials for LifeScan blood glucose monitor systems

**D. Type of Test:**

Quality control materials

**E. Applicant:**

Bionostics, Inc.

**F. Proprietary and Established Names:**

The proposed device will be marketed under the following three product names:

LifeScan OneTouch Select Control Solution

LifeScan OneTouch Ultra Control Solution

LifeScan OneTouch Vita Control Solution

**G. Regulatory Information:**

| <b>Product Code</b>  | <b>Classification</b> | <b>Regulation Section</b>  | <b>Panel</b>            |
|--|-----------------------|--|-------------------------|
| JJX, Single (Specified) Analyte Controls (Assayed and Unassayed) | Class I, reserved     | 21 CFR § 862.1660, Quality control material (assayed and unassayed). | Clinical Chemistry (75) |

**H. Intended Use:**

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The LifeScan OneTouch Select Control Solution is intended for use to verify the performance of the LifeScan OneTouch Select blood glucose monitoring test system at a glucose level printed on the test strip vial. The LifeScan OneTouch Select Control Solution is intended for use by healthcare professionals and people with diabetes mellitus at home. For *In Vitro* Diagnostic Use.

The LifeScan OneTouch Ultra Control Solution is intended for use to verify the performance of the LifeScan OneTouch Ultra Family and the OneTouch Ping™

Meter Remote blood glucose monitoring test systems at a glucose level printed on the test strip vial. The LifeScan OneTouch Ultra Control Solution is intended for use by healthcare professionals and people with diabetes mellitus at home. For *In Vitro* Diagnostic Use.

The LifeScan OneTouch Vita Control Solution is intended for use to verify the performance of the LifeScan OneTouch Vita blood glucose monitoring test system at a glucose level printed on the test strip vial. The LifeScan OneTouch Vita Control Solution is intended for use by healthcare professionals and people with diabetes mellitus at home. For *In Vitro* Diagnostic Use.

3. Special conditions for use statement(s):  
For prescription and over the counter use.
4. Special instrument requirements:  
OneTouch Ultra Blood Glucose Meter  
OneTouch Ping Meter Remote  
OneTouch Select Blood Glucose Meter  
OneTouch Vita Blood Glucose Meter

**I. Device Description:**

This single level control solution consists of glucose in water with buffers and stabilizers, a viscosity adjusting agent, a preservative, and a dye. The device is formulated to provide glucose values representative of fasting blood glucose values in non-diabetic subjects. The active ingredient, glucose, is the same analyte measured in blood specimens by the relevant blood glucose test systems. The viscosity and other proprietary characteristics of the solution have been modified to mimic the measurement of blood specimens with this non-biological, non-toxic, aqueous solution. The product does not contain red blood cells, and so, cannot be used to assess hematocrit effects on glucose measurement. The solution has a red color to enhance its visibility.

**J. Substantial Equivalence Information:**

|  |                         |
|--|-------------------------|
| Predicate device name                    | Predicate 510(k) number |
| LifeScan OneTouch Ultra Control Solution | k022769                 |

Comparison with predicate:

| Similarities and Differences |   |  |   |  |
|------------------------------|---|--|---|--|
| Item                         | Proposed Device                           |  |   | Predicate Device<br>(k022769)                    |
|                              | LifeScan OneTouch Select Control Solution | LifeScan OneTouch Ultra Control Solution | LifeScan OneTouch Vita Control Solution |  |
| Indications for Use          | Same                                      | Same                                     | Same                                    | LifeScan control solution is intended for use to |

|                      |                          |  |                        |  |
|----------------------|--------------------------|--|------------------------|--|
|                      |                          |  |                        | verify the performance of blood glucose monitoring systems. The control solution is intended for use by healthcare professionals and people with diabetes mellitus at home.<br>For <i>In Vitro</i> Diagnostic Use. |
| Analyte              | Same                     | Same   | Same                   | D-glucose  |
| Matrix               | Same                     | Same   | Same                   | Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives and other non-reactive ingredients.  |
| Number of Levels     | Same                     | Same   | Same                   | 1  |
| Target Value         | Same                     | Same   | Same                   | Approximately 115 mg/dL  |
| Blood Glucose Meters | LifeScan OneTouch Select | LifeScan OneTouch Ultra<br><br>LifeScan OneTouch Ping Meter Remote | LifeScan OneTouch Vita | LifeScan OneTouch Ultra<br><br>LifeScan OneTouch Select<br><br>LifeScan OneTouch Vita  |

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

- ISO 15197: In-vitro diagnostic test systems
- ISO 14971:2007 Medical Devices - Application of risk management to medical devices
- ISO13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- ISO 15223-1 Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied
- ISO 18113-2 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) ... for professional use
- ISO 18113-4 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) ... for self testing
- EN13640: Stability Testing of In Vitro Diagnostic Reagents

**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):*

*Traceability:*

The control solution is formulated gravimetrically to contain 115 mg glucose/dL solution using scales traceable to NIST traceable mass standards. The solution is verified to conform to specification by testing on YSI 2300 calibrated using NIST traceable calibrators and in parallel to internally prepared standard solutions traceable to NIST SRM 917d.

*Value assignment:*

Control ranges are provided on the test strip vial label. Following all other manufacturing lot acceptance testing, each lot of test strips is tested using 100 test strips and 50 meters designated for value assignment testing. For value assignment to be valid, the imprecision from this series of measurements must be  $\leq 2.75$  mg/dL SD, and at least 95% of all measurement values must fall within a range assigned as mean of this series; -10% to +20%.

*Stability:*

Stability characteristics of the Lifescan OneTouch Ultra, Select and Vita Control Solutions stored at 2-8°C and 30°C were determined under closed and opened conditions in real time stability studies. The closed and unopened Control Solutions were assayed using an YSI2300 analyzer every three months for 27 months and the results were compared. The study satisfied the acceptance criteria and supports the closed (unopened) bottle claim of 27 months.

An open vial stability of 90 days was demonstrated by comparing the results of material from vials stored at 30°C/86°F (opened once per week) to unopened vials stored at 2-8°C using an YSI2300 analyzer. The recommendations in the labeling are to store control solutions at room temperature and additional warnings are given to not refrigerate control solutions.

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 expected values are provided on the test strip vial label.

**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.