

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

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

k113764

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Control Materials for glucose test system.

**D. Type of Test:**

Not Applicable.

**E. Applicant:**

Bionostics, Inc.

**F. Proprietary and Established Names:**

Glucose Meter-Check<sup>®</sup> Solution for Infopia

**G. Regulatory Information:**

<b>Product Code</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
JJX	Class I, reserved	21 CFR § 862.1660 Quality Control Material (Assayed and Unassayed)	Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

Please see intended use below.

2. Indication(s) for use:

Glucose Meter-Check<sup>®</sup> Solution for Infopia is intended for use to verify the performance and correct operation of Infopia blood glucose monitoring test systems utilizing Infopia glucose test strips. Glucose Meter-Check Solution for Infopia is intended for use by

healthcare professionals and people with diabetes mellitus at home.

3. Special conditions for use statement(s):

For prescription Use.

4. Special instrument requirements:

To be used on the Infopia blood glucose monitoring test systems.

**I. Device Description:**

Glucose Meter-Check® Solution for Infopia is a buffer aqueous solution with D-glucose containing viscosity modifier, preservatives and other nonreactive ingredients, none of biological origin. This device is packaged as one level.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Infopia Element Control Solution

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

k072369

3. Comparison with predicate:

Attribute	Glucose Meter-Check® Solution for Infopia (Candidate Device)	Infopia Element Control Solution (Predicate - k072369)
Indication for use / Intended for Use	Glucose Meter-Check® Solution for Infopia is intended for use to verify the performance and correct operation of Infopia blood glucose monitoring test systems utilizing Infopia glucose test strips. Glucose Meter-Check Solution for Infopia is intended for use by healthcare professionals and people with diabetes mellitus at home.	Same
Target range	88 – 132 mg/dL	94 – 140 mg/dL
Test System (Instrumentation / technology)	Infopia blood glucose monitoring test systems.	Same
Storage Temperature after opening	3 months at 2-30°C	Same
Shelf life	24 months at 2-30°C	12 months

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

ISO 15197 In Vitro Diagnostics Test Systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

ISO 14971:2007 Medical Devices - Application of risk management to medical devices.

ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes.

ISO 15223-1:2007 Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied.

ISO 18113-2:2009 In vitro diagnostic medical devices -- Information supplied by the manufacturer (labeling) -- Part 2: In vitro diagnostic reagents for professional use

ISO 18113-4:2009 In vitro diagnostic medical devices -- Information supplied by the manufacturer (labeling) -- Part 4: In vitro diagnostic reagents for self-testing

**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 Glucose Meter-Check® Solution for Infopia is made of an in house glucose material. The glucose used on this preparation is traceable to SRM 917 via measurement by YSI 2300 calibrated with solutions provided by YSI traceable to SRM 917.

Control Value Assignment

For the Glucose Meter-Check® Solution for Infopia, the analytical values for each production lot of material are confirmed by comparison of new production lots of material to the Reference Lot of product with the same formulation in parallel measurement on the YSI 2300 reference method in order to maintain lot-to-lot variability within close tolerances.

Stability

Real time stability study protocols and acceptance criteria were described and found to be acceptable.

The claimed Control stability is 24 months at 2-30 °C for unopened vials and at 3 months for open vials when stored at 2-30°C.

*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:

A lot specific example of the expected range for the Glucose Meter-Check® Solution for Infopia is 88 – 132 mg/dL.

**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.