

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

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

k103450

**B. Purpose for Submission:**

New device

**C. Measurand:**

Glucose

**D. Type of Test:**

Quality Control Material

**E. Applicant:**

Fujirebio Diagnostics, Inc.

**F. Proprietary and Established Names:**

FDI Glucose Control Solution for FreeStyle

**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, Calibrator, Multi-Analyte Mixture
4. Panel:  
  
Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

See indications for use statement below.

2. Indication(s) for use:

For *in vitro* diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the FreeStyle Blood Glucose Monitor

3. Special conditions for use statement(s):

For *in vitro* diagnostic use only

4. Special instrument requirements:

FreeStyle Blood Glucose Monitor

**I. Device Description:**

The FDI Glucose Control Solution for FreeStyle is a ready to use solution consisting of a viscosity-adjusted, aqueous liquid control solution containing a known quantity of glucose. The device is packaged in plastic dropper tipped bottles for easy application of the control solutions to the test strips and a red coloration to aid the user to visually confirm application of the control. Each vial contains enough solution (3.6 mL) to run 75 tests. The device is non-hazardous and contains no human or animal derived materials.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

FDI Glucose Control Solution

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

k102260

3. Comparison with predicate:

<b>Similarities and Differences</b>		
<b>Item</b>	<b>Device FDI Glucose Control Solution for FreeStyle</b>	<b>Predicate (k102260) FDI Glucose Control Solution</b>
Intended Use	Intended to assess the performance of Blood Glucose Monitor	Same

Similarities and Differences		
Item	Device FDI Glucose Control Solution for FreeStyle	Predicate (k102260) FDI Glucose Control Solution
Blood Glucose Systems	FreeStyle Blood Glucose Systems	FreeStyle Lite Blood Glucose Systems
Matrix	Aqueous	Same
Analytes	Glucose	Same
Preparation	Liquid, ready-for-use	Same
Number of Levels	1	Same
Target Range (mg/dL)	70 to 120	75 to 125
Packaging	3.6 mL/level	Same

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

None were referenced.

**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:*

Glucose (0.88 g/L) is added to the control solution. The solution is analyzed on commercially available clinical chemistry analyzer against a standard (88 mg/dL) traceable to the NIST standard reference material 917c. The sponsor states that the 88 mg/dL standard is manufactured in accordance with the NIST “Instructions for Use as a Standard in Clinical Applications” which accompanies the certificate of analysis for SRM917c.

*Stability:*

Stability characteristics of the FDI Glucose Control Solution for FreeStyle were determined by real time and open vial stability studies. Three replicates of control material are assayed using a commercially available clinical chemistry analyzer. The studies support the claimed shelf life of 24 months at 59 to 86°F (15 to 30°C) and the claimed open vial stability of 90 days (after opening) when stored at room temperature at 59 to 86°F (15 to 30°C).

*Value assignment:*

Control solutions, with an expected value of 88 mg/dL, are tested using a commercially available clinical chemistry analyzer, and then using the FreeStyle meter and test strips. The target range for the control solution is established using three FreeStyle test strip lots, with 10 replicates per test strip lot. Acceptable ranges are based on pre-determined acceptance criteria for glucose recovery for each lot. The glucose control value ranges are lot dependent; therefore the range for each lot is printed on the control solution vial label. These ranges may differ from the range printed on the test strip vial. The control solution labeling instructs the user compare their control result with the range on the control vial label.

*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:

Expected values are provided on control solution vial labels for each lot.

**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 substantial equivalence decision.