

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

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

k102260

**B. Purpose for Submission:**

New device

**C. Measurand:**

Quality control materials for a blood glucose monitor

**D. Type of Test:**

Quality Control Materials

**E. Applicant:**

Fujirebio Diagnostics, Inc. (FDI)

**F. Proprietary and Established Names:**

FDI Glucose Control Solution

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
JJX	Class I, reserved	21 CFR 862.1660 Quality Control Material	Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

Refer to indication for use below

2. Indication(s) for use:

The FDI Glucose Control Solution is intended 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 FreeStyle Lite Blood Glucose Monitor.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use only

For over the counter use

3. Special instrument requirements:

FreeStyle Lite Blood Glucose Monitor

**I. Device Description:**

The FDI Glucose Control Solution consists of a viscosity-adjusted, aqueous liquid control solution containing a known quantity of glucose. The product 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. The product is non-hazardous and contains no human or animal derived materials.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

AbT Glucose Control Solution

2. Predicate 510(k) number:

k083549

4. Comparison with predicate:

See below

Characteristic/ Aspect	Predicate Device (k083549)	New Product
Indications for Use	Same	Intended for in vitro diagnostic use by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of Blood Glucose Monitor
Number of Levels	1	1
Analyte	Same	Glucose
Target (mg/dL)	Same	88
Target Range (mg/dL)	80 – 130	75 – 125
Container	Same	Plastic bottle with dropper-tip
Fill Volume	Same	3.6 mL
Color	Same	Red
Matrix	Same	Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, and other non-reactive ingredients
Target Population	Same	Professional and home use

**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:

The glucose added to the control material (0.88g/L) is tested using a clinical chemistry analyzer's glucose assay against an 88 mg/dL standard traceable to the NIST 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.

Value Assignment:

The control material with an expected value of 88 mg/dL is tested using a commercially available clinical chemistry analyzer. Value assignment protocol for Free Style Lite blood glucose monitor involve repeated testing on the glucose monitor to obtain the mean and variance values. The assigned range is based upon a percentage of the obtained mean ( $\pm 21\%$ ). The expected results may vary slightly with each lot. The expected range is listed in the product insert for the glucose control material. In addition, the product insert for this device alerts the user to use the range indicated in this control's product insert rather than the range provided in the glucose test strip product's insert that applies to another commercially available control material.

Stability:

Shelf life of the control was determined using real time and open vial stability. The control is stored at room temperature.

Real time stability

The control material was assayed using a commercially available clinical chemistry analyzer and glucose assay every other month for 24 months. Three replicates of the control material were assayed for each level.

The study satisfied the acceptance criteria and supports the shelf life claim of 24 months.

Open vial stability

Two sets of control solution vials were used to perform the study. One set of sample vials were opened everyday for 10 minutes and closed. Each week these samples were assayed and compared against the unopened set of vials. Each measurement was done in triplicate. The experiment was carried out for 13 weeks.

The data satisfied the acceptance criteria and support the open vial stability claim of 90 days (after opening) in the labeling.

*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 the vial labels and Package insert.

**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.