

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

A. 510(k) Number:

k081915

B. Purpose for Submission:

New Device

C. Measurand:

Quality control materials for blood glucose monitoring systems

D. Type of Test:

Not applicable

E. Applicant:

Fujirebio Diagnostics Texas, Inc.

F. Proprietary and Established Names:

FDTX 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 indications for use 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 Contour Blood Glucose Monitor.

3. Special conditions for use statement(s):

Over-The-Counter Use

4. Special instrument requirements:

Bayer Ascensia Contour Blood Glucose Monitor

I. Device Description:

The FDTX 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 nonhazardous and contains no human or animal derived materials.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Ascensia Microfill Control Solution

2. Predicate K number(s):

k023657

3. Comparison with predicate:

Both devices contain D-Glucose and no human or animal derived materials.

Similarities		
Item	Device	Predicate
Number of levels	1	1

Similarities		
Item	Device	Predicate
Analyte	glucose	glucose
Container	Plastic bottle with dropper	Plastic bottle with dropper

Differences		
Item	Device	Predicate
Fill Volume	3.6 mL	2.5 mL
Matrix	Aqueous glucose solution	Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, and other non-reactive ingredients

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

CLSI EP5-A, Evaluation of the Precision Performance of Clinical Chemistry Devices

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):

The D-Glucose used in this control is traceable to an in-house glucose preparation. Values are assigned by repeat analysis using three different lots of test strips. The mean and standard deviation are used to establish the acceptable range for each glucose monitoring system.

Stability characteristics of the FDTX Glucose Control Solution were determined using real-time studies. The unopened shelf-life is 24 months and the open vial stability is 90 days at the recommended storage of 36 °F to 86

°F.

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:

An acceptable range for each glucose monitoring system is printed in the labeling. When using this control material, users are to compare their control results to the

range printed in the labeling for the system being used (rather than the range printed on the test strip vial or carton.)

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.