

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

A. 510(k) Number:

k080273

B. Purpose for Submission:

Notification of intent to manufacture and market the device: FDTX Glucose Control Solution for the Bayer Ascensia Breeze 2 Blood Glucose Monitor.

C. Measurand:

Glucose

D. Type of Test:

Quality Control

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 Indication(s) for use

2. Indication(s) for use:

The FDTX Glucose Control Solution is 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 Breeze 2 Blood Glucose Monitor.

3. Special conditions for use statement(s):

Over the Counter Use.

4. Special instrument requirements:

Bayer Ascensia Breeze 2 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 test strips and a red coloration to aid the user to visually confirm application of the control. The device is non-hazardous and contains no human or animal derived materials.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bayer Ascensia Breeze 2 Normal Control and Liberty Normal Glucose Control Solution

2. Predicate K number(s):

k062347 and k060426 respectively

3. Comparison with predicate:

Characteristic/ Aspect	Predicate Device No. 1	Predicate Device No. 2	New Product
Name	Ascensia BREEZE 2 Control Normal	Liberty Glucose Normal Control Solution	FDTX Glucose Control Solution
510(k), Date	k062347, 11/21/2006	k060426, 3/09/2006	k080273
Number of Levels	1	1	1
Analyte	Glucose	Glucose	Glucose
Target value (mg/dL)	100	100	100
Container	Plastic bottle with dropper tip	Plastic bottle with dropper tip	Plastic bottle with dropper tip
Fill Volume	2.5 mL	3.6 mL	3.6 mL
Color	Blue	Red	Red
Matrix	Blue solution containing a measured amount of glucose.	Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, and other nonreactive ingredients	Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, and other nonreactive ingredients
Indications for Use	For use as quality control check to verify that the BREEZE 2 meter and test strips are working properly.	To check the performance of the Bayer Ascensia DEX 2/DEX and BREEZE Blood Glucose Monitors.	To check the performance of the Bayer Ascensia BREEZE 2 Blood Glucose Monitor.
Target Population	Professional and home use	Professional and home use	Professional and home use

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

CLSI EP-5: Evaluation of Precision Performance of Quantitative Measurement
Methods; Approved Guideline, Second Edition

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

Control values are traceable to an in-house standard prepared from NIST material SRM917b. The control material is analyzed on the sponsor's reference analyzer in one run of 10 replicates and values must fall within $\pm 5\%$ of the target value of the standard.

Expected Values (Control Range Determination)

The expected values were determined by repeat testing on Bayer Ascensia Breeze 2 using three lot numbers of test strips. Statistical analysis of the data obtained resulted in one range for the three lots. The expected results may change with each new lot, but the control range is listed in the product insert. In addition, the product insert alerts the user to use the control range indicated in the control's product insert rather than the glucose test strip product's insert.

Stability

- Shelf Life: Real time stability studies were conducted. Protocols and acceptance criteria were reviewed and found to be acceptable.
- Open Vial Stability: Control material was divided into two pools—Test and Control. The Control Group remained unopened until testing against the Test Group. The Test Group was opened daily and allowed to stand at room temperature for 10 minutes, then closed and stored at room temperature. One vial of the Test Group and one vial of the Control Group were checked weekly by the sponsor's reference method. Results from the study supported a 13 week open vial stability.

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:

Not applicable

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.