

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

A. 510(k) Number:

k060426

B. Purpose for Submission:

Notification of intent to manufacture and market the device: Liberty Glucose Normal Control Solution for the Bayer Ascensia DEX 2/DEX and Breeze Glucose Monitors

C. Measurand:

Glucose

D. Type of Test:

Quality Control Material

E. Applicant:

Liberty Healthcare Group, Inc

F. Proprietary and Established Names:

Liberty Glucose Normal Control Solution

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1660

2. Classification:

Class I

3. Product code:

JJX, single (specified) analyte controls (assayed and unassayed)

4. Panel:

75, Chemistry

H. Intended Use:

1. Intended use(s):

See indication for use below.

2. Indication(s) for use:

Liberty Glucose Normal 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 Bayer Ascensia DEX 2/DEX and Breeze Blood Glucose Monitors.

3. Special conditions for use statement(s):

Over the Counter use

4. Special instrument requirements:

Bayer Ascensia DEX 2/DEX and Breeze Blood Glucose Monitors

I. Device Description:

The Liberty Glucose Normal Control Solution consists of a viscosity-adjusted, aqueous liquid containing a known quantity of glucose. The product is packaged in plastic dropper tipped bottles for easy application of the control solution to the test strips. A red coloration is present to aid the user visually in confirming the 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):

Bayer Ascensia Autodisc Normal Control and Liberty Glucose Control

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

k963500 and k052980, respectively

3. Comparison with predicate:

Characteristic/ Aspect	Ascensia Autodisc Normal Control (predicate device)	Liberty Glucose Control (predicate device)	Liberty Glucose Normal Control Solution
510(k)	k963500	k052980	
Number of levels	1	1	1
Analyte	Glucose	Glucose	Glucose
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	Red	Red	Red
Matrix	Red solutions containing a measured amount of Glucose	Buffered aqueous solution of D- Glucose, viscosity modifiers, preservatives and other non-reactive ingredients	Buffered aqueous solution of D- Glucose, viscosity modifiers, preservatives and other non-reactive ingredients
Indications for use	For use with the appropriate Ascensia/Glucometer Blood Glucose meter and Ascensia Autodisc Test strip Disc as a quality control check to verify the accuracy of blood glucose test results.	Used to check the performance of Medisense Blood Glucose Systems only.	To check the performance of the Bayer Ascensia DEX and 2/DEX and Breeze Blood Glucose Monitors
Target Population	Professional and Home use	Professional and Home use	Professional and Home use

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. Stability characteristics of the Liberty Glucose Control were determined using the Arrhenius model of accelerated elevated temperature and real time studies to determine estimated storage stability at 2 – 30 °C. Open vial stability was determined to be 90 days at 2-30 °C.

The expected values were determined by repeat testing on each glucose monitor (Bayer Ascensia DEX 2/DEX and Breeze). Statistical analysis of the data obtained resulted in one range for the three glucose monitors. 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.

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.