

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

A. 510(k) Number:

k063855

B. Purpose for Submission:

New Device

C. Measurand:

Quality control materials for glucose

D. Type of Test:

N/A

E. Applicant:

Liberty Healthcare Group, Inc.

F. Proprietary and Established Names:

Liberty Control Solutions (Normal Level and High Level)

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1660 Quality control material (assayed and unassayed)
2. Classification:
Class I
3. Product code:
JJX, single (specified) analyte controls (assayed and unassayed)
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

For in vitro diagnostic use (i.e. for external use only) by healthcare professional and in the home by people with diabetes mellitus to assess the performance of the Liberty Blood Glucose Monitoring System.

2. Indication(s) for use:

See intended use section above

3. Special conditions for use statement(s):

Over-The-Counter Use

3. Special instrument requirements:

Liberty Blood Glucose Monitoring System

I. Device Description:

The Liberty Control Solutions are liquid glucose control solutions for use with the Liberty Blood Glucose Monitors. Each control consists of a buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, red dye, and other non-reactive ingredients. The device is non-sterile, over-the counter product and is intended for external use only. It is non-hazardous and contains no human or animal derived materials.

The product is packaged in a plastic dropper tipped bottle for easy application of the control solution to the test strip and contains sufficient volume (3.6 mL) to run 75 tests. A red coloration is included to aid the user to visually confirm application of the control.

J. Substantial Equivalence Information:

1. Predicate device name(s):
AgaMatrix Liberty Control Solution
2. Predicate 510(k) number(s):
k052762
3. Comparison with predicate:
Both devices contain D-Glucose and is non-hazardous and contains no human or animal derived materials.

Similarities		
Item	Device	Predicate
Indications for Use	Used to check the performance of Liberty Blood Glucose Monitoring System.	Used with the Liberty Meter and Test Strips as a quality control check to verify the accuracy of blood glucose test results.
Target Population	Professional and home use	Professional and home use
Matrix	Buffered Aqueous Solution	Buffered Aqueous Solution
Container	Plastic bottle with dropper-tip	Plastic bottle with dropper-tip
Analytes	Glucose	Glucose
Number of Levels	2	2

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 control level.

Stability characteristics of the Liberty Glucose Control MID 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:

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.