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

A. 510(k) Number:
k060481

B. Purpose for Submission:
New Device

C. Measurand:
Glucose

D. Type of Test:
Not applicable

E. Applicant:
Liberty Healthcare Group, Inc.

F. Proprietary and Established Names:
Liberty Glucose Control

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:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   Liberty Glucose Control 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 TheraSense FreeStyle Blood Glucose 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:
   TheraSense FreeStyle Blood Glucose Monitor

I. Device Description:

The Liberty Glucose Control 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):
   TheraSense FreeStyle Control, Liberty Glucose Control

2. Predicate 510(k) number(s):
   k031260, k052980

4. Comparison with predicate:
   All devices contain D-Glucose, are non-hazardous and contain no human or animal derived materials.

Similarities			
Item	Liberty Glucose Control (device)	TheraSense FreeStyle Control	Liberty Glucose Control (predicate)
Indications for Use	Used to check the performance of TheraSense FreeStyle Blood Glucose Monitor	Used to check the performance of TheraSense FreeStyle Blood Glucose Monitor	Used to check the performance of Medisense Blood Glucose Systems.
Target Population	Professional and home use	Professional and home use	Professional and home use
Matrix	Buffered aqueous solution of D-Glucose, viscosity modifier, preservatives, and other non-reactive ingredients	Buffered aqueous solution of D-Glucose, viscosity modifier, preservatives, and other non-reactive ingredients	Buffered aqueous solution of D-Glucose, viscosity modifier, preservatives, and other non-reactive ingredients
Analyte	Glucose	Glucose	Glucose
Number of Levels	1	1	1
Container	Plastic bottle with dropper-tip	Plastic bottle with dropper-tip	Plastic bottle with dropper-tip

Differences			
Item	Liberty Glucose Control (device)	TheraSense FreeStyle Control	Liberty Glucose Control (predicate)
Fill Volume	3.6 mL	4.0 mL	3.6 mL

K. Standard/Guidance Document Referenced (if applicable):
CLSI EP5-A, Evaluation of the Precision Performance of Quantitative Measurement Methods

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 ºC. Open vial stability was determined to be 90 days at 2-30 ºC.

   The expected values were determined by repeat testing on the TheraSense FreeStyle glucose monitor. Statistical analysis of the data was used to determine the range for the monitor. Expected results may change with each lot, but the control will list the range in the product insert. In addition, the product insert alerts the user to use the 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.