

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

A. 510(k) Number:

k071433

B. Purpose for Submission:

New device

C. Measurand:

Quality control material for glucose

D. Type of Test:

Not applicable

E. Applicant:

Specialty Medical Supplies (SMS)

F. Proprietary and Established Names:

SMS Glucose Control

G. Regulatory Information:

1. Regulation section:

21CFR Section 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:

See intended use section 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 TheraSense FreeStyle Blood Glucose System.

3. Special conditions for use statement(s):

Over-the-Counter use

4. Special instrument requirements:

TheraSense FreeStyle Blood Glucose Meter.

I. Device Description:

The product is a one-level, aqueous liquid glucose control solution for use with the TheraSense FreeStyle Blood Glucose System. The glucose 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, 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):

TheraSense FreeStyle Control
Liberty Glucose Control

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

k031260
k060481

3. Comparison with predicate:

The subject device and both predicate devices contain D-Glucose and no human or animal derived materials.

Similarities		
Item	Device	Predicates
Target Users	Professional and home use	same
Matrix	Buffered Aqueous solution	same
Packaging	Plastic bottle with dropper tip	same
Analytes	Glucose	same
Number of levels	1	same

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, 10 replicates per strip lot. For each lot, the mean, standard deviation, and % CV were calculated. A representative range of values for this product is 85 – 129 mg/dL.

Stability characteristics of the SMS Glucose Control 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.