

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

**A. 510(k) Number:**

k151742

**B. Purpose for Submission:**

Device modification resulting from a recall

**C. Measurand:**

Glucose

**D. Type of Test:**

Quality control solution

**E. Applicant:**

Bayer Healthcare LLC, Diabetes Care

**F. Proprietary and Established Names:**

Contour Next Control Solution

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:

Class I

3. Product code:

JJX

4. Panel:

Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

See Indication(s) for use below.

2. Indication(s) for use:

Contour Next Control Solutions are aqueous glucose solutions intended for use in self-testing by people with diabetes as a quality control check to ensure that the Contour Next Blood Glucose Monitoring Systems are working properly.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use only

4. Special instrument requirements:

To be used with Contour Next Blood Glucose Monitoring Systems

**I. Device Description:**

The Contour Next Control Solution is an aqueous quality control material, used as a quality control check to ensure that the Bayer Contour Next Blood Glucose Monitoring Systems are reading accurately. Two levels are available (Level 1 and Level 2). Each level contains a controlled amount of glucose, preservatives and other non-reactive ingredients. The range of acceptable values is printed on the test strip vial labels.

The candidate device has been reformulated by the addition of a surfactant to reduce adherence of the solution to the inside of the neck of the bottle which can result in out-of-range results and results not marked as control results by the meter.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Contour Next Control Solution

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

K111268

3. Comparison with predicate:

Similarities/Differences		
Item	Candidate Device Contour Next Control Solution	Predicate Device Contour Next Control Solution (k111268)
Indications for use	Contour Next Control Solutions are aqueous glucose solutions intended for use in self-testing by people with diabetes as a quality control check to ensure that the Contour Next Blood Glucose Monitoring Systems are working properly.	Same
Levels	Level 1 and Level 2	Same
Surfactant	Yes	No
Glucose concentration	0.025% Level 1 0.067% Level 2	0.03% Level 1 0.07% Level 2
Storage temperature	9 – 30 <sup>0</sup> C (18 month closed vial, 6 month open vial)	Same

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

Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material

**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 Contour Next Control Solution is traceable to NIST SRM #917

Control Solution Value Assignment:

Value assignment for the control solutions is the same as the predicate, and is based on replicate reading on each of thirty-six instruments and the range is assigned as  $\pm 11\%$  relative to the calculated mean.

Control Solution Stability:

Stability testing protocols and acceptance criteria for the reformulated glucose control solutions were reviewed and found to be acceptable. The manufacturer claims a shelf life stability of 18 months and an open-vial stability of 6 months at the recommended storage temperatures of 9°C to 30°C, which is unchanged from the predicate device.

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:

The acceptable range for each control solution level is printed on the test strip vial label. Users ensure that the results they obtain when using the control material are within those ranges.

**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.