

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k130265

B. Purpose for Submission:

Modification of the Contour Next EZ Blood Glucose Meter with three changes made to the glucose measuring algorithm to enhance low temperature measurements, allow blood re-application, and enhance moisture detection.

C. Measurand:

Glucose in capillary whole blood from fingertip.

D. Type of Test:

Quantitative amperometric assay (FAD-glucose dehydrogenase)

E. Applicant:

Bayer Health Care LLC, Diabetes Care

F. Proprietary and Established Names:

CONTOUR® NEXT EZ Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1345 Glucose Test System

2. Classification:

Class II

3. Product code:

LFR - Glucose dehydrogenase, glucose

NBW - Blood glucose test system, Over-the-Counter

4. Panel:

Clinical Chemistry - 75

H. Intended Use:

1. Intended use(s):

Refer to indications for use below.

2. Indication(s) for use:

The CONTOUR® NEXT EZ blood glucose monitoring system is an over the counter (OTC) device utilized for self-testing by persons with diabetes at home for the quantitative measurement of glucose in whole blood, is for single-patient use only, and should not be shared.

The CONTOUR® NEXT EZ blood glucose monitoring system is indicated for use with fresh fingertip capillary whole blood samples. The clinical utility of this device is to aid in monitoring the effectiveness of your diabetes control program.

The CONTOUR® NEXT EZ blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

The CONTOUR® NEXT test strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use only.

For over the counter use.

Not for neonatal use.

Not for use in Critically Ill

Not for screening or diagnosis of diabetes mellitus.

Single-patient use systems are for use on single patients only and should not be shared.

The following Contraindications statement is included in the labeling:

Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.

4. Special instrument requirements:

CONTOUR® NEXT EZ Blood Glucose Meter

I. Device Description:

The CONTOUR®NEXT EZ Blood Glucose Meter consists of a small handheld blood glucose meter that utilizes dry reagent test strips for the measurement of glucose in capillary whole blood by persons with diabetes. The modified device is capable of detecting low sample when sensor is either severely under-filled (less than half-full) or moderately under-filled (more than half-full), and allowing the user to re-apply more blood onto the same strip within 20 seconds.

Liquid CONTOUR®NEXT Control Solution (level 1 and 2) and the CONTOUR®NEXT Test Strips were cleared under k111268. Contour®NEXT level 2 control solution is included in the kit.

J. Substantial Equivalence Information:

1. Predicate device name:
CONTOUR®NEXT EZ Blood Glucose Monitoring System)
2. Predicate 510(k) number:
K111268
3. Comparison with predicate:

Item	CONTOUR® NEXT EZ Blood Glucose Monitoring System; Predicate Device (k111268)	CONTOUR® NEXT EZ Blood Glucose Monitoring System; Modified Device (k130265)
Similarities with Predicate		
Intended Use	Intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Detection method	Quantitative amperometric assay (FAD-glucose dehydrogenase)	Same
Sample type	Capillary whole blood	Same
Sample sites	Fingertip	Same
Test Strip	CONTOUR®NEXT Test Strips	Same
Control Solution	CONTOUR®NEXT Control Solutions (Level 1 and 2)	Same
Test Strip Underfilled Detection	Yes	Same
Calibration	Autocoding (no coding for users)	Same
Measurement Range	20-600 mg/dL	Same
Hematocrit Range	15-65%	Same
Blood Sample Volume	0.6 uL	Same
Reaction Time	5 seconds	Same
Operating Conditions	41-113°F / 10-93% RH	Same
Battery Type	Two 3-volt lithium batteries (CR2032 or DL2032)	Same

Illuminated Strip Port	No	Same
Operational Buttons	Two button - choice selection and menu/power button	Same
Sound	A beep sounds when the meter is turned on, a test strip is inserted, when a test strip is filled with blood, or when a test result appears on the display. Two beeps sound when the meter turns off or to indicate an error. Twenty beeps sound for a programmed reminder.	Same
Meter life	Five years	Same
Validated Product Used for Cleaning & Disinfection	Clorox Germicidal wipes	Same
Test Reminder	Yes	Same
Display (technology)	Segmented (LCD), Alphanumeric characters and icons	Same
Display visibility	Daylight only	Same
Error Message Displays	No, but error codes and symbols are displayed and their meanings are provided in the system's User Guide	Same
Communication Link to Computer	Via serial to USB cable	Same
Test Results in Memory	480 Results	Same
Meter Materials	Case Top/Bottom: ABS Buttons: AS	Same
Before and After Meal Marker	Yes, when used in advanced setting	Same

Differences from Predicate

Characteristic	CONTOUR® NEXT EZ Blood Glucose Monitoring System; Predicate (k111268)	CONTOUR® NEXT EZ Blood Glucose Monitoring System; Modified Device (k130265)
Glucose Calculation Algorithm that ensures consistent performance at low temperatures (<15°C)	No	Yes

Improved blood detection algorithm to allow blood reapplication when sensor is either severely under-filled (less than half-full) or moderately under-filled (more than half-full)	No	Yes
Error detection algorithm to detect test strips that have been damaged by exposure to excessive moisture	No	Yes

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

ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

ISO 14971: Medical Devices - Application of risk management to devices.

IEC 61326-1, IEC 61326-2-6: Electrical equipment for measurement, control and laboratory use - EMC requirements.

IEC 61010-1, IEC 61010-2-101: Safety requirements for electrical equipment for measurement, control and laboratory use.

L. Test Principle:

CONTOUR NEXT EZ blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and the mediator. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation is required.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Previously cleared under k111268.

b. *Linearity/assay reportable range:*

Previously cleared under k111268.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Previously cleared under k111268.

- d. *Detection limit:*
Previously cleared under k111268.
 - e. *Analytical specificity:*
Previously cleared under k111268.
 - f. *Assay cut-off:*
Not applicable
2. Comparison studies:
- a. *Method comparison with predicate device:*
Previously cleared under k111268.
 - 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 product labeling contains the following statement: “*Non diabetic plasma glucose concentrations should be <100 mg/dL in the fasting state and <140 mg/dL in the post-prandial state.* You should consult with your healthcare professional for glucose values specific to your needs.*”
- *Reference: American Diabetes Association: Standards of Medical Care in Diabetes – 2013. Diabetes Care 2013; volume 36, supplement 1: S13.

N. Instrument Name:

CONTOUR NEXT EZ glucose meter

O. System Descriptions:

1. Modes of Operation:

Amperometric.

Does the applicant’s device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes or No

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:

Yes or No

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes or No

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

This device is intended for use with fingertip capillary whole blood which is applied directly to the test strip.

5. Calibration:

The device is factory calibrated and requires no additional calibration by the user.

6. Quality Control:

The sponsor recommends the use of Level 1 and Level 2 CONTOUR NEXT control solutions with this system. Control solution level 2 is included in the kit. These controls can be purchased using the contact information provided in the user manual. When the test strip is inserted into the glucose meter, control material can be measured by following the instructions for "Control Solution Testing" provided in the user guide for the meter. The CONTOUR NEXT EZ meter will automatically recognize and mark the control result. Control results will not be included in blood glucose averages.

P. The "Performance Characteristics" Section above:

The studies performed to mitigate the risks associated with the three modifications to the glucose measuring algorithm, support the algorithm changes.

Other:

1) Altitude Study:

Previously cleared under k111268.

2) Sample Volume

Previously cleared under k111268.

3) Usability Study

Previously cleared under k111268.

4) Readability Assessment

Previously cleared under k111268.

5) Customer Service Telephone Number

Customer service is available 24 hours a day, 7 days a week. The toll free phone number is 1-800-348-8100 for customer support.

6) EMC Testing

Previously cleared under k111268.

7) Cleaning and Disinfection

Previously cleared under k111268.

Q. Proposed Labeling:

There were no labeling changes made to all the labeling cleared under k111268.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.