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

A. 510(k) Number:

k111268

B. Purpose for Submission:

New device

C. Measurand:

Glucose in capillary whole blood

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

CONTOUR NEXT Glucose Test Strips

CONTOUR NEXT Control Solutions

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345 Glucose Test System

   21 CFR 862.1660 Quality Control Material

2. Classification:

Class II

Class I, reserved

3. Product code:

   LFR - Glucose dehydrogenase, glucose

   NBW - Blood glucose test system, over the counter

   JJX - Single (Specified) Analyte Controls

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.

   The CONTOUR NEXT control solutions are aqueous glucose solutions intended for use in self-testing by people with diabetes as a quality control check.

3. Special conditions for use statement(s):

   For *in vitro* diagnostic use only. For prescription and over the counter use.

Not for neonatal use
Not for screening or diagnosis of diabetes mellitus
Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients

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

4. Special instrument requirements:

   CONTOUR NEXT EZ Blood Glucose Meter

I. Device Description:

The CONTOUR NEXT EZ blood glucose monitoring system is for single-patient use for the measurement of glucose in whole blood. The system consists of a hand-held CONTOUR NEXT EZ blood glucose meter, CONTOUR NEXT blood glucose test strips, CONTOUR NEXT control solutions (Level 1 and Level 2), Bayer's MICROLET2 lancing device, and Bayer's MICROLET lancets.

J. Substantial Equivalence Information:

1. Predicate device name:

   CONTOUR Blood Glucose Monitoring System

2. Predicate 510(k) number:

   k062058

3. Comparison with predicate:

Comparison Table		
Item	New Device (k111268)	Predicate (k062058)
Intended Use	Intended for quantitative determination of glucose.	Same
Detection method	Modified-quantitative amperometric assay (FAD-glucose dehydrogenase)	Quantitative amperometric assay (FAD-glucose dehydrogenase)
Sample type	Capillary whole blood	Capillary, venous, and arterial whole blood samples and neonatal blood samples
Sample sites	Fingertip	Fingertip, palm, forearm, and neonates' heels
Test Strip Underfilled Detection	Yes	No
Calibration	Autocoding	same
Measurement Range	20-600 mg/dL	10-600 mg/dL

Comparison Table		
Item	New Device (k111268)	Predicate (k062058)
Hematocrit Range	15-65%	0-70%
Humidity	10-93% RH	same
Altitude	Up to 20,674 feet	Up to 10,000 feet
Blood Sample Volume	0.6 uL	same
Reaction Time	7 seconds	5 seconds
Operating Conditions	5-45°C/10-93% RH	same
Storage Conditions	Test Strips: 5-30°C Controls: 9-30°C	Test Strips: 15-30°C Controls: 15-30°C
Battery Type	Two CR2032 (3-volts) or DL2032	same
Controls	modified formulation- 2 levels	Low/Normal/High

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

1. ISO 15197. *In vitro* diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
2. ISO 14971. Medical devices-Application of risk management to medical devices.
3. EN 61010-1:2001. Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 1. General requirements.
4. IEC/EN 61010-2-101. Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 2-101. Particular requirements for *in vitro* diagnostic (IVD) medical equipment.
5. EN 61326-1:2006. Electrical equipment for measurement, control, and laboratory use. EMC Requirements. General requirements.

L. Test Principle:

The 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:

   Precision studies were performed based on ISO 15197 guidelines. Repeatability studies were carried out by testing venous blood at five venous blood glucose concentrations (HCT 43%) ranging from 47-332 mg/dL. Three lots of CONTOUR

NEXT glucose test strips were tested on ten CONTOUR NEXT EZ glucose meters with ten replicates per meter. To evaluate intermediate precision, the sponsor tested three levels of CONTOUR NEXT control solutions on ten CONTOUR NEXT EZ glucose meters and one lot of CONTOUR NEXT glucose test strips over the course of 10 days. The mean, standard deviation (SD), and coefficients of variation (CV) were determined for each level as summarized below:

Repeatability Data Summary			
Venous Blood Samples			
Glucose Interval (mg/dL)	**Grand Mean (mg/dL)**	**Pooled SD (mg/dL)**	**Pooled CV (%)**
(30-50)	47	0.8	1.7
(51-110)	84	1.1	1.3
(111-150)	139	2.1	1.5
(151-250)	201	2.6	1.3
(251-400)	326	5.0	1.5
Intermediate Precision Data Summary			
Control Samples			
Glucose Level (mg/dL)	**Grand Mean (mg/dL)**	**Pooled SD (mg/dL)**	**Pooled CV (%)**
1	42	0.7	1.6
2	122	1.4	1.1
3	357	5.5	1.5

b. Linearity/assay reportable range:

A linearity study was carried out using seven different levels of venous whole blood samples which were either glycolyzed or supplemented with a glucose stock solution to reach glucose concentrations ranging from 15-600 mg/dL (42% HCT) as determined by the YSI reference method. Each glucose level was measured with three lots of CONTOUR NEXT glucose test strips on eight CONTOUR NEXT EZ glucose meters. Least-square regression analysis is summarized below.

Linearity Data Summary				
Regression Data	**Test Strip Lot 1**	**Test Strip Lot 2**	**Test Strip Lot 3**	**Combined Data**
Equation	y = 0.969(x) + 2.046	y = 0.957(x) + 0.30	y = 0.975(x) + 1.34	y = 0.967(x) + 1.246
Slope - 95% CI	0.963 to 0.976	0.953 to 0.961	0.970 to 0.980	0.964 to 0.970
Intercept - 95% CI	-0.338 to 4.429	-1.068 to 1.668	-0.527 to 3.206	0.084 to 2.408
r^2	0.997	0.999	0.998	0.998

The claimed reportable range of the CONTOUR NEXT EZ blood glucose monitoring system is 20 to 600 mg/dL. The sponsor evaluated that samples below or above the claimed measuring range are flagged by the meter as "LO" or "HI", respectively, by testing extremely low (5 mg/dL) and extremely high (900, 1200, 1500, and 1800 mg/dL glucose samples on eight meters and three lots of test strips.

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

Traceability

The CONTOUR NEXT EZ blood glucose monitoring system is factory calibrated and further calibration by the user is not necessary for operation. The calibration is traceable to NIST (dry-D-glucose) SRM 917a.

Test Strip Stability

Stability testing protocols and acceptance criteria for the Contour NEXT EZ test strips were reviewed and found to be acceptable. The manufacturer claims shelf life stability and open-vial stability of 18 months at the recommended storage temperatures of 5-30°C.

Controls Value Assignment and Stability

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

Stability testing protocols and acceptance criteria for the 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 3 months at the recommended storage temperatures of 9°C to 30°C.

d. *Detection limit:*

The measuring range of the CONTOUR NEXT EZ blood glucose monitoring system is 20 to 600 mg/dL. This range was verified by the linearity study (see section M.1.b of this decision summary).

e. *Analytical specificity:*

Interference studies were performed by adding common endogenous and exogenous substances to a pool of fresh whole blood at 80 and 300 mg/dL plasma glucose and calculating bias relative to a control of the same samples. A minimum of ten replicates per sample were collected for each substance on at least five CONTOUR NEXT EZ meters with each of three lots of CONTOUR NEXT glucose test strips. Significant interference was defined as >10% bias. No significant interference was

observed up to the levels shown in the table below for the following interfering substances:

Substance	No Interference at Listed Level
Endogenous Substance	
Bilirubin	54 mg/dL
Cholesterol	1168 mg/dL
Creatinine	34 mg/dL
Hemoglobin	2 g/dL
Triglycerides	4709 mg/dL
Uric Acid	59 mg/dL
Exogenous Substance	
Acetaminophen	35 mg/dL
Ascorbic Acid	10 mg/dL
Caffeine	7 mg/dL
Dopamine	4 mg/dL
Ephedrine	11 mg/dL
Galactose	336 mg/dL
Gentisate	112 mg/dL
Glutathione	17 mg/dL
Ibuprofen	56 mg/dL
Icodextrin	2 mg/dL
L-Dopa	5 mg/dL
Maltose	336 mg/dL
Methyl-Dopa	3.4 mg/dL
Salicylate	112 mg/dL
Tetracycline	4 mg/dL
Tolazamide	112 mg/dL
Tolbutamide	112 mg/dL

The study showed that xylose has a significant interference at 6 mg/dL. The sponsor has added the following limitations on the product labeling:
"Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference."
"Certain substances occurring in the blood naturally (uric acid, bilirubin) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect results." An interferences table is shown in the test strips package insert.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

User Performance Evaluation:

In a user performance evaluation, 115 untrained lay users tested their own capillary fingerstick blood samples on three randomized test strip lots on the CONTOUR NEXT EZ system using labeling material provided with the device. Subjects were people with diabetes who had not used the test system before and had no training prior to testing with the device. Data were compared to glucose values obtained with the YSI reference method covering the glucose range of 49-492 mg/dL. Study results are summarized below:

Lay-user Study Regression Statistics vs. YSI	
Number of samples (n)	115
Range of YSI Glucose Values (mg/dL)	49-492
Slope	0.97
95% CI	(0.95-0.99)
Intercept	3.8
95% CI	(1.1-6.5)
R square	0.98

Lay-user Study Results			
Glucose < 75 mg/dL			
Within ± 5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL	
6/7 (85.7%)	7/7 (100%)	7/7 (100%)	
Glucose ≥ 75 mg/dL			
Within ± 5 %	Within ±10 %	Within ± 15 %	Within ± 20%
83/108 (76.9%)	104/108 (96.3%)	107/108 (99.1%)	108/108 (100%)

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):

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   The product labeling contains the following statement: "Non diabetic plasma glucose concentrations are normally maintained within a relatively narrow range, roughly 70-110 mg/dL in a fasting state.* You should consult with your healthcare professional for expected values specific to your needs."

   *Reference: Longo DL, et al.: Harrison's Principles of Internal Medicine, 18th edition. 2011: 3003.

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 __X___ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:
   Yes _____ or No __X __

2. Software:

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

   Yes ___X_____ or No _____

3. Specimen Identification:

   The device is capable of distinguishing control solutions from fingertip capillary whole blood samples. The device is also capable of detecting low sample and allowing the user

to re-apply more blood onto the same strip within 20 seconds. 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. These controls are available when requested by the customer 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. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. Hematocrit Study:

   A study was performed to evaluate the blood hematocrit (HCT) effect on the performance of the CONTOUR NEXT EZ blood glucose monitoring system across the measuring range of the assay (40, 90, 180, 275, 360, 450, and 550 mg/dL). Venous blood samples were tested in replicates of twelve using three lots of strip and six meters. Glucose concentrations at each HCT level (15%, 20%, 25%, 40%, 55%, 60%, and 65%) were compared with results obtained at 40% HCT and the YSI-2300 reference method. Data were found adequate. The sponsor included the following limitation in the label: CONTOUR NEXT test strip results are not significantly affected by hematocrit levels in the range of 15% to 65%.

2. Altitude Study:

   The effect of altitude was evaluated inside and outside a glove box purged with ultra pure nitrogen to simulate a high altitude condition. Two lots of the CONTOUR NEXT test strips were tested on five meters in duplicate with 41 and 65% HCT whole blood supplemented with 50, 100, and 400 mg/dL plasma glucose. The mean assay results obtained were compared to YSI reference method values and data were found adequate. The sponsor included the following limitation in the label: "Altitude: Up to 20, 674 feet (6,301 meters) does not significantly affect results".

3. Temperature and Humidity Studies

Studies were performed to evaluate the effect of temperature and humidity on the performance of the CONTOUR NEXT EZ blood glucose monitoring system at 80 and 350 mg/dL glucose levels using whole blood samples. Testing was completed using fifteen replicates per sample, two lots of CONTOUR NEXT test strips, and five CONTOUR NEXT EZ meters. Meters were evaluated while exposed to different temperature and humidity combinations to support the claimed ranges of 5-45°C and 10-93% RH.

4. Sample Volume

Sample volume studies were performed at 100 and 300 mg/dL blood glucose (42% HCT) using three lots of CONTOUR NEXT glucose test strips in triplicate on each of eight CONTOUR NEXT EZ glucose meters at different sample volumes (0.4, 0.55, 0.6, and 0.7 uL). Test results support the claimed use of 0.6 uL of sample. The new system has a sample re-application feature in which the user can reload sample within a 20 seconds window prior to receiving the error code.

5. Usability Study

A usability study was performed to assess the readability of the labeling by recruiting lay users (aged 18-79 yrs old) who were provided with the test kit containing labeling for the US market. Participants varied in age, education, country of origin, and were about evenly divided between men and women. Data from a questionnaire provided to these lay users indicate that the users found the device easy to use and the instructions for use were written in a way that makes it easy to use. Data from this study were found adequate.

6. Readability Assessment

Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (user guide, test strip package insert, quick reference guide, and control solution package insert) were written at the grade level no higher than 7.8.

7. 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.

9. EMC Testing

EMC testing was evaluated and certified by Underwriters Laboratories and a certificate was issued to Bayer on February 14, 2011.

10. Cleaning and Disinfection

The device system is intended for *single-patient use* only. Disinfection efficacy studies were performed on materials comprising the Contour NEXT EZ glucose meter and the Microlet 2 lancing device by outside commercial laboratory testing services demonstrating complete inactivation of live virus with Clorox Germicidal Wipes (EPA Reg. No: 67619-12). The sponsor also conducted robustness studies and demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 260 cleaning and disinfection cycles to simulate 5 years of use by lay-users. Each robustness cycle tested consisted of one pre-clean wipe and one disinfecting wipe. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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