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

A. 510(k) Number:

k160682

B. Purpose for Submission:

New device

C. Measurand:

Glucose in fresh capillary whole blood from the fingertip and palm.

D. Type of Test:

Quantitative, Amperometric method, Glucose dehydrogenase (FAD)

E. Applicant:

Ascensia Diabetes Care

F. Proprietary and Established Names:

CONTOUR NEXT ONE Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345

2. Classification:

   Class II

3. Product code:

   NBW, Blood glucose test system, over the counter

   LFR, Glucose Dehydrogenase, Glucose

4. Panel:

   75, Clinical Chemistry

H. Intended Use:

1. Intended use:

   See indications for use below.

2. Indications for use:

   The Contour® Next ONE blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips or palm. The Contour® Next ONE blood glucose monitoring system is intended to be used by a single person and should not be shared. The Contour® Next ONE blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program.

   The Contour® Next ONE blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing (palm) should be done only during steady state times (when glucose is not changing rapidly). The Contour® Next test strips are for use with the Contour® Next ONE blood glucose meter to quantitatively measure glucose in fresh capillary whole blood drawn from the fingertips or palm.

   The system is intended for in vitro diagnostic use only.

3. Special conditions for use statement(s):
   - For in vitro diagnostic use only.
   - Do not use for diagnosis of, or screening of diabetes
   - Alternative site testing should be done only when glucose is not changing rapidly.
   - The Contour Next ONE meter is not indicated for neonatal use
   - The system should not be used to test critically ill patients.
   - The system should not be used by 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.
   - Do not calibrate a continuous glucose monitoring device from an AST result.
   - Do not calculate an insulin dose based on an AST result.
   - This system has not been tested at altitudes higher than 20,674 feet (6301 meters).

4. Special instrument requirements:

   CONTOUR NEXT ONE Blood glucose meter

I. Device Description:

The Contour® NEXT One Blood Glucose Monitoring System consists of the Contour Next One blood glucose meter, the Contour Next test strips (sold separately; previously cleared in k111268), two levels of the Contour Next control solutions (sold separately; previously cleared in k151742), lancing device, lancets, clear endcap (sold separately), and user manual. The key feature of the new system is the ability to automatically transfer data to a smart device using Bluetooth communication, allowing users to interact with their blood glucose results with a custom application called Contour® Diabetes App. Additionally the Contour® NEXT One meter includes a revised glucose calculation algorithm to further improve the level of accuracy compared to the Contour NEXT system.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   CONTOUR NEXT USB Blood Glucose Meter

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

   k150942

3. Comparison with predicate:

Similarities		
Item	Candidate Device CONTOUR NEXT ONE (k160682)	Predicate Device CONTOUR NEXT USB (k150942)
Intended Use	Intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips or palm as an aid in monitoring the effectiveness of a diabetes control program	Same
Test strip	Contour Next Test Strips	Same
Test Strip Chemistry	FAD-GDH	Same
Measuring Range	20-600 mg/dL	Same
Blood sample volume	0.6µL	Same
Controls	CONTOUR NEXT Control	Same
Control solution ranges	Level 1 and Level 2	Same
Automatic calibration	Yes	Same

Differences		
Item	Candidate Device CONTOUR NEXT ONE (k160682)	Predicate Device CONTOUR NEXT USB (k150942)
Wireless technology	Bluetooth Low Energy (BLE) to smart phones and tablets	No wireless communication
PC connection	Micro-USB port	USB port
Display	LCD with 7-segments and icons	Graphical OLED with text
Battery type	CR 2032	Lithium Polymer rechargeable
Test memory	800 results	2000 results
Sample re-application capability	60-second re-application time	30 second re-application time

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

None

L. Test Principle:

The active ingredients on the Contour® NEXT Test Strips are the enzyme, FAD dependent glucose dehydrogenase (FAD-GDH), and an electron mediator. When a blood sample fills the reaction zone of the test strip, a chemical reaction occurs in which the FAD-GDH enzyme causes electrons to pass from glucose molecules to co-factor and the mediator in the test strip. New software in the Contour® NEXT One meter converts the electrical current measurement into glucose concentration and displays the result on the meter LCD screen.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within run precision was performed using five venous whole blood samples spiked with glucose to five levels. Three test strip lots and ten meters were used for this study. The samples tested ranged from 40-336mg/dL. Each sample was tested ten times on each of ten meters. The average, SD and CV was calculated for each sample. The combined mean, pooled standard deviation and pooled CV for each glucose concentration were calculated using results from all three reagent lots. The results are summarized below:

Glucose level (mg/dL)	Lot #	Mean (mg/dL)	SD (mg/dL)	% CV
30-50	1	43.7	0.81	1.85
	2	43.7	0.93	2.13
	3	43.8	0.96	2.18
	Combined	43.7	0.90	2.06
51-110	1	77.7	0.97	1.25
	2	77.3	1.36	1.76
	3	77.9	1.33	1.71
	Combined	77.6	1.23	1.59
111-150	1	129.5	1.86	1.43
	2	129.1	1.73	1.34
	3	129.2	1.68	1.30
	Combined	129.3	1.76	1.36
151-250	1	206.1	3.01	1.46
	2	204	3.12	1.53
	3	205.8	2.43	1.18
	Combined	205.3	2.87	1.40
251-400	1	332.9	3.41	1.02
	2	331.4	4.45	1.34
	3	330.9	3.86	1.17
	Combined	331.7	3.93	1.19

The intermediate precision evaluation was performed with three levels of glucose control solutions using three test strip lots and ten Contour NEXT ONE Glucose meters. Each sample was tested in ten replicates for ten days. The average, SD and CV was calculated for each sample. The combined mean, pooled standard deviation and pooled CV for each glucose concentration were calculated using results from all three reagent lots. The results are summarized below:

Control Solution Level	Lot #	Mean (mg/dL)	SD (mg/dL)	%CV
Low	1	41.8	0.51	1.22
	2	42.2	0.64	1.52
	3	42.1	0.62	1.46
	Combined	42.0	0.59	1.41
Normal	1	123.6	1.50	1.22
	2	123.5	1.39	1.12
	3	123.7	1.58	1.28
	Combined	123.6	1.49	1.21
High	1	361.4	4.16	1.15
	2	363.2	6.35	1.75
	3	364.5	5.44	1.49
	Combined	363.1	5.39	1.48

b. Linearity/assay reportable range:

The claimed measuring range for this device is 20-600 mg/dL.

Linearity was evaluated using twenty four Contour NEXT ONE meters, three lots of test strips and venous whole blood samples adjusted to twelve glucose levels (17, 40, 77, 136, 196, 256, 315, 375, 435, 495, 555 and 615 mg/dL). For each sample, twenty four replicate Contour NEXT ONE readings were obtained with each of three Contour Next lots. The values from the Contour NEXT ONE meters were compared with those obtained from the reference method. The results from regression analysis are summarized below:

Lot #1: $y=0.967x+0.99$; $R^2 = 0.999$
Lot #2: $y=1.000x+0.57$; $R^2 = 0.999$
Lot #3: $y=0.988x+1.49$; $R^2 = 0.999$

The results of the study support the sponsor's claimed glucose measurement range of 20 to 600 mg/dL. The meter will display "LO" when the result is less than 20 mg/dL and "HI" when result is greater than 600 mg/dL. Studies were performed by the sponsor demonstrating that these features function as intended.

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

Contour Next Test strip stability protocols and acceptance criteria were reviewed and for to be acceptable in k111268. The manufacture claims shelf life stability and open vial stability of 24 months when stored at 41°F- 86°F (5°C-30°C) and 10-80% R.H.

Contour Next Control solution stability protocols and acceptance criteria were reviewed and for to be acceptable in k151742. The manufacturer claims shelf life stability for the Contour Next Control Solutions of 18 months and an open vial stability of 6 months when stored at 48-86°F (9°-30°C).

d. Detection limit:

See linearity study in Section M1b above.

e. Analytical specificity:

Analytical specificity was assessed for twenty three endogenous and exogenous substances with two venous blood samples with two levels of glucose (approximately 80mg/dL and 300mg/dL). Each sample was divided into a test pool containing the potential interfering substance and a control pool. The absolute and % difference between the test and control samples measured on the Contour Next One meter were calculated and the concentration tested at which no significant interference (as defined by the sponsor as within ±10 mg/dL difference at 80mg/dL level and within ±10% difference at 300mg/dL level relative to the control sample) was observed is presented in the table below:

Compound	The highest concentration at which no significant interference is observed (mg/dL)
Acetaminophen	33
Ascorbic Acid (Vitamin C)	11.6
Bilirubin	38.9
Cholesterol	1242
Creatinine HCl	34
Dopamine HCl	4.2
Galactose	360
Na Gentisate	58
Glutathion	12
Hemoglobin (g/dL)	0.8
Ibuprofen	80
L-dopa	5.4
Maltose	480
Methyl-dopa	3.4
Pralidoxine Iodide (PAM)	64.8
Salicylate	120
Tolazamide	81
Tolbutamide	50
Triglycerides	1410
Uric Acid	39.5
Xylose	11.7
Icodextrin	2.2

The sponsor has the following limitation in their labeling:
Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

To assess system accuracy, results from the Contour Next One Glucose Monitoring System were compared to those obtained on YSI 2300 reference analyzer.

Fingerstick samples from 117 participants with glucose concentrations ranging from 36.5-599.8 mg/dL glucose obtained on the reference were measured using one of three test strip lots by technicians. In addition, 6 contrived samples with glucose concentrations at <50 mg/dL or >400 mg/d were prepared and tested. The Contour Next One results relative to reference method are summarized in the tables below:

Contour Next One vs. Reference for fingerstick samples
For glucose concentrations <75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
9/9 (100%)	9/9 (100%)	9/9 (100%)

For glucose concentrations ≥75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
83/114 (72.8%)	110/114 (96.5%)	114/114 (100%)	114/114 (100%)

Linear regression results Contour Next One vs. whole blood PCA-HK reference (N=123):

$y=0.95x + 1.2$, $R^2=0.996$

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):

To assess the performance of the Contour Next One Blood Glucose Monitoring System in the hands of lay users the sponsor performed a study with 372 lay user participants. Participants were provided with labeling for the Contour Next One blood glucose monitoring system. No other training or prompting was provided to the subjects. The subjects then performed their own testing without any assistance from the technician. Results were analyzed by comparing blood glucose results from

finger stick samples using the Contour Next One meter obtained by the lay users against the reference method value (YSI 2300). The samples ranged from 32.2 to 458 mg/dL as measured by the reference method. The results are summarized in the tables below:

Lay-user finger stick results Contour Next One vs. YSI 2300 reference:

For glucose concentrations <75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
82.4% (14/17)	94.1% (16/17)	100% (17/17)

For glucose concentrations ≥ 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
81.1% (288/355)	96.3% (342/355)	99.7% (354/355)	100% (355/355)

Regression Analysis finger stick results Contour Next One vs. YSI 2300 reference by lay users: $y=1.006x - 0.725$, $R^2=0.9876$

Alternative Site Test (Palm Site) by Lay Users:

To assess the performance of the Contour Next One Blood Glucose Monitoring System using palm as the sampling site in the hands of the intended users 366 lay-user participants measured his/her own samples, while another blood sample from each lay user was also collected by a technician and measured by the reference method (YSI 2300). Results were analyzed by comparing blood glucose results from the Contour Next One meter obtained by the lay user against the YSI 2300 reference value. The samples ranged from 45.0 to 458 mg/dL glucose as measured by the reference method. The results are summarized in the tables below:

Lay-user palm results Contour Next One vs. YSI 2300 reference:

For glucose concentrations <75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
55.6% (5/9)	77.8% (7/9)	100.0% (9/9)

For glucose concentrations ≥ 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
70.6% (252/357)	89.6% (320/357)	96.9% (346/357)	98.6% (352/357)

Regression Analysis palm results Contour Next One vs. YSI 2300 reference by lay users: $y=1.03x - 4.15$, $R^2=0.9726$

4. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:

The fasting adult blood glucose range for a person without diabetes:

Time	**Range (mg/dL)**
Fasting and before meals	Less than 100mg/dL
1-2 hours after meals	Less than 140mg/dL

American Diabetes Association. Standards of medical care in diabetes—2016. Diabetes Care. 2016;39(supplement 1):S15.

N. Instrument Name:

CONTOUR Next ONE Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

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 ___X_____ or No _____

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:

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:

The device is intended to be used with capillary whole blood from the finger and palm The whole blood is applied directly to the test strip by capillary action therefore there are no special handling or storage issues.

5. Calibration:

This is a non-coding device; therefore no calibration is required by the user.

6. Quality Control:

   The CONTOUR Next Control Solutions Levels 1 and 2 are used to check that the meter and test strips are working properly together as a system.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In the "Performance Characteristics" Section above:

1) **Altitude study:** To evaluate the effect of altitude on the Contour Next One Blood Glucose Monitoring System, venous blood samples at approximately 45, 67, 134 and 400 mg/dL levels were tested under simulated altitude conditions. The evaluation included 10 meters and 2 test strip lots. The meter results were compared to those obtained with the reference method (YSI 2300). The results demonstrate acceptable bias to the reference to support the claims in the labeling that altitudes up to 20,674 feet have no significant effect on blood glucose measurements from the Contour Next One Blood Glucose Monitoring System.

2) **Hematocrit:** A study was performed to evaluate the effect of blood hematocrit on the performance of the Contour NEXT ONE Blood Glucose Monitoring System. Venous blood samples at 4 glucose levels (40, 120, 350 and 520 mg/dL) were tested using three Contour Next Test Strip lots and 24 meters. Glucose concentrations at each hematocrit level (15, 30, 42, 55 and 65%) for were compared with the reference method (YSI 2300). The resulting % bias relative to YSI demonstrated acceptable performance across the claimed hematocrit range of 15 – 65%.

3) **Operating Temperature and Humidity:** Operating temperature and humidity conditions were evaluated using 15 meters and 2 test strip lots with venous whole blood samples at four glucose levels (40, 120, 350, and 525 mg/dL). The following temperature and humidity conditions were tested: 5°C/10% RH, 5°C/93%, 25°C/50%, 45°C/10%, 45°C/93%. The results support the sponsor's claimed operating temperature from 41°F to 113°F (5°C to 45°C) and 10% to 93% Relative Humidity.

4) **EMC testing and Electrical Safety Studies:** The sponsor provided appropriate documentation certifying that electromagnetic (EMC) and wireless coexistent testing was performed and the Contour NEXT ONE Blood Glucose Monitoring Systems was found to be compliant.

5) **Readability Assessment:** A Flesch-Kincaid Grade Level assessment was conducted on the CONTOUR Next ONE User Guide and CONTOUR Next One Quick reference guide and the results demonstrated that the labeling was written at lower than 8th grade level.

6) **Infection control studies:** The device is intended for single patient use only. Disinfection efficacy was performed on the materials comprising the meter demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfecting agents,

Clorox® Healthcare Bleach Germicidal Wipes (EPA reg. 67619-12) and Clorox® Healthcare Hydrogen Peroxide Wipes (EPA reg. 67619-25). Robustness studies were performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 260 cleaning and disinfection cycles (representing weekly disinfection for 5 years, the expected lifetime of the meter) with Clorox Germicidal Wipes (EPA Registration #67619-12). The subject device labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7) Customer service is available 8:00 am through midnight Eastern Time, 365 days a year. Toll free phone number is 1-800-348-8100 for Bayer Diabetes Care customer support.

8) This device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the submission was received prior to the finalization of the guidance documents.

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.