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

I Background Information:

A 510(k) Number

K193407

B Applicant

Ascensia Diabetes Care

C Proprietary and Established Names

Contour® next GEN Blood Glucose Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Glucose in fresh capillary whole blood drawn from the fingertips

C Type of Test:

Quantitative amperometric assay (glucose dehydrogenase-FAD)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Contour® next GEN Blood Glucose Monitoring System consists of the Contour® next GEN meter, Contour® NEXT test strips and the Contour® Diabetes app.
The Contour® next GEN Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips. The Contour® next GEN Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Contour® next GEN 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 GEN Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use.

The system is intended for in vitro diagnostic use only.

C Special Conditions for Use Statement(s):

- OTC - Over The Counter
- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.
- Not to be used for the diagnosis of or screening for diabetes
- Not for Alternative Site Testing (AST)
- The system should not be used to test critically ill patients and should not be used by persons with reduced peripheral blood flow.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hypoxia state, or a hyperglycemic-hyperosmolar state, with or without ketosis.
- Not indicated for neonatal use.
- This system has not been tested at altitudes higher than 20,674 feet (6,301 meters).
- Severe dehydration (excessive water loss) may cause inaccurate results.
- For single-patient use only.

D Special Instrument Requirements:

Contour® next GEN Blood Glucose Meter

IV Device/System Characteristics:

A Device Description:

The Contour® next GEN Blood Glucose Monitoring System has been developed for use with the currently marketed Contour® NEXT Test Strip. The new system utilizes amperometric biosensor technology to quantitatively measure the glucose concentration in whole blood in five seconds. This new Contour® next GEN blood glucose monitoring system includes the meter, test strips, the Contour® Diabetes App, a lancing device, lancets, User Guide, Quick Reference Guide, carrying case, registration/warranty card, and control solution. The Contour® Diabetes App is compatible with Android (operating systems 5.0, 6.0. 7.0, 8.0, 9.0. 10.0, and 11.0) and Apple devices (iOS 12.0, 13.0, and 14.0)

B Principle of Operation:

The Contour® next GEN Blood Glucose Monitoring System measures the amount of glucose in whole blood quantitative using fresh capillary whole blood from the fingertip amperometrically. The reaction of glucose dehydrogenase and an electron mediator in the test strip with glucose in the sample produces an electrical current which is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration, which is displayed by both the meter meter's display screen and the Contour® Diabetes app.

C Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☒	☐
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   Contour® next GEN Blood Glucose Monitoring System

2. Specimen Identification:

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

3. Specimen Sampling and Handling:

   The system is intended to be used with capillary whole blood from the fingertip. The whole blood sample is applied directly to the test strip by capillary action. Samples are to be tested immediately upon collection.

4. Calibration:

   The meter does not require calibration or coding by the user. The meter is automatically coded.

5. Quality Control:

   Contour® Next Control Solution are aqueous solutions that can be purchased separately. Recommendations on when to perform a control solution testing are provided in the labeling. The acceptable range for each control level is printed on the test strip bottle or on the bottom of the test strip box. The user is cautioned not to use the meter if the control result falls outside these ranges and to contact Customer Service. The control solution readings are not included in the average of the patient results when the measurements are performed in the "QC" measurement mode. When in QC measurement mode the meter will automatically mark the result as a control solution test.

V Substantial Equivalence Information:

A Predicate Device Name(s):

CONTOUR® NEXT ONE Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

K160682

C Comparison with Predicate(s):

D

Device & Predicate Device(s):	K193407	K160682
Device Trade Name	Contour® next GEN Blood Glucose Monitoring System	Contour® Next One Blood Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Quantitatively measure glucose in fresh capillary whole blood drawn from the fingertips by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program.	Same
Test Strip	Contour® Next	Same
Test strip chemistry	FAD-GDH	Same

Device & Predicate Device(s):	K193407	K160682
Sample re-application capability	60-second re-application time	Same
General Device Characteristic Differences		
Alternative Site Testing	No	Yes (palm)
Test Result Trends (Averages)	Yes	No
Test Reminders	Yes	No

VI Standards/Guidance Documents Referenced:

- IEC 60601-1-2:2014, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability:

A repeatability study was conducted with the Contour® next GEN blood glucose monitoring system using five venous whole blood specimens with glucose target levels of 40, 75, 130, 200, and 336 mg/dL. Each level was tested with three lots of test strips in replicates of 10 on each of 10 meters for a total of 300 results per glucose concentration and 1500 results total. Results are summarized below:

Lot	Reference Glucose, mg/dL	Mean (mg/dL)	SD (mg/dL)	CV %
1	41.5	42.0	1.0	2.5
	79.6	81.1	1.3	1.6
	134.5	135.2	1.9	1.4
	218.1	216.5	3.2	1.5
	350.1	343.6	4.3	1.2
2	39.0	40.1	1.2	3.0
	77.6	78.3	1.4	1.8

Lot	Reference Glucose, mg/dL	Mean (mg/dL)	SD (mg/dL)	CV %
	141.7	139.6	2.1	1.5
	214.1	211.7	2.5	1.2
	347.2	340.9	4.2	1.2
3	37.0	38.3	1.1	2.9
	75.5	76.5	1.3	1.7
	139.2	137.6	2.0	1.4
	214.1	209.6	4.0	1.9
	345.2	339.0	4.6	1.3
Pooled	39.2	40.1	1.1	2.8
	77.6	78.6	1.3	1.7
	138.5	137.5	2.0	1.5
	215.4	212.6	3.3	1.6
	347.5	341.2	4.4	1.3

Intermediate precision:

Intermediate measurement precision was evaluated using 5 control solutions at glucose levels within the ranges of 30-50, 51-100, 111-150, 151-250, and 251-400 mg/dL. For each level, three lots of test strips were tested in replicates on each of ten meters on ten separate days for a total of 300 results per glucose level. Results are summarized below:

Lot	Control level	Mean (mg/dL)	SD (mg/dL)	CV %
1	1	43.8	0.7	1.5
	2	84.7	1.1	1.3
	3	127.3	1.5	1.2
	4	220.3	3.1	1.4
	5	370.5	7.0	1.9
2	1	42.9	0.5	1.2
	2	83.6	0.9	1.1
	3	125.8	1.4	1.1
	4	219.2	2.4	1.1
	5	370.6	6.5	1.8
3	1	42.5	0.6	1.4
	2	83.4	1.2	1.4

Lot	Control level	Mean (mg/dL)	SD (mg/dL)	CV %
	3	125.7	1.7	1.4
	4	220.1	3.1	1.4
	5	370.6	6.1	1.6
Pooled	1	43.1	0.6	1.4
	2	83.9	1.1	1.3
	3	126.3	1.5	1.2
	4	219.9	2.9	1.3
	5	370.6	6.5	1.8

2. Linearity:

To evaluate linearity, a study was conducted using twelve blood samples adjusted to glucose concentrations covering the reportable range of 20 to 600 mg/dL. The specific glucose values by the YSI analyzer were 22.5, 39.5, 78.9, 139.3, 199.5, 262.5, 314.3, 380.3, 433.3, 498.5, 556.5, and 592.0 mg/dL. Results on the candidate device were compared to YSI 2300 Stat Plus Glucose Analyzer. Each glucose level was tested in replicates of 24 using three test strip lots. Plasma glucose concentrations were measured on the YSI 2300 analyzer before and after each blood specimen was tested on meters, and the average of results was used as the comparison value. Proportionally weighted least squares regression produced the following:

Lot	Slope	y-intercept	r^2
1	0.975	1.91	0.9980
2	0.996	0.72	0.9980
3	0.989	1.45	0.9984

The results of the study support the sponsor's claimed glucose measuring range of 20 – 600 mg/dL. If the concentration of a sample is less than 20 mg/dL, the result is flagged by the meter as LO. If the concentration of a sample is greater than 600 mg/dL, the result is flagged by the meter as HI. The low and high functions were validated and were demonstrated to function as intended.

3. Analytical Specificity/Interference:

The sponsor performed a study to evaluate the effect of common exogenous and endogenous compounds with the potential to interfere with the glucose measurements.

Venous blood samples were prepared at glucose concentrations of approximately 60 mg/dL (3.3 mmol/L), 120 mg/dL (6.7 mmol/L) and 260 mg/dL (14.4 mmol/L) and were divided into a test pool with the potential interferent added and a control sample with no added interferent.

One measurement was made with a test strip from each of three lots on each of the 10 meters using each of the three glucose levels. This produces 10 measurements per meter per lot for each glucose concentration, resulting in a total of 90 measurements for each interferent.

Results on the candidate meter from the test samples were compared to results obtained on the candidate meter from the control sample. The highest tested concentrations at which no significant interference was observed are presented in the following table:

Potential Interferent	Highest concentration tested with no significant interference (mg/dL)
Acetaminophen (Paracetamol)	20
Ascorbic acid	6
Conjugated Bilirubin	50
Unconjugated Bilirubin	40
Cholesterol	500
Creatinine	15
Dopamine	0.09
Galactose	60
Gentisic acid	1.8
Reduced Glutathione	5
Hemoglobin	1000
Ibuprofen	50
L-Dopa (Levodopa)	0.75
Maltose	480
Mannitol	1800
Methyl-Dopa	2
Pralidoxime Iodide (PAM)	8.1
Salicylic acid	60
Sodium	396
Tolbutamide	100
Tolazamide	40
Triglyceride	1500
Uric acid	24
Sorbitol	1.1
Xylitol	1.1
Lactitol	1.1
Maltitol	1.1
Isomalt	1.1

All concentrations of xylose tested demonstrated significant interference with the device system; therefore, the sponsor includes the following in their labeling: Xylose: Do not use during or soon after xylose absorption therapy as this could cause an erroneous result with your meter.

4. Assay Reportable Range:

   The assay reportable range is 20-600 mg/dL.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The system is traceable to the National Institute of Standards and Technology (NIST) SRM 917 glucose reference material.

   Test Strip Stability:

   The Contour® Next Test Strip stability protocols and acceptance criteria were reviewed and found to be acceptable in k111268 for the strips packaged in vials and in k191286 for the individually foil wrapped test strips.

   The manufacture claims shelf life and opened-vial stability of 24 months when stored at temperatures between 41°F–86°F and 10%–80% Relative Humidity (RH).

   For individually foil wrapped test strips, the shelf life is also 24 months when stored at temperatures between 41°F–86°F and 10%–80% Relative Humidity (RH).

6. Detection Limit:

   The claimed reportable range for this assay is 20-600 mg/dL and is supported by the linearity study above (section VII.A.2).

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Not applicable.

9. Carry-Over:

   Not applicable. The device uses single-use test strips.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See the lay user study below, section VII.C3, for system accuracy in the hands of the intended user.

2. Matrix Comparison:

   Not applicable. The device is only intended for use with fresh capillary whole blood from a fingerstick.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Lay-user Performance study:

   To assess the performance of the Contour® next GEN Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a lay user study with 371 English speaking participants who were untrained (including naïve users and people with diabetes). The data was collected using three test strip lots at two clinical trial sites. The participants were responsible for obtaining their own fingertip capillary sample and performing a blood glucose test using only the instructions from the product labeling written in English.

   Results were analyzed by comparing the blood glucose results obtained by the lay users with the Contour® next GEN Next Gen Blood Glucose Monitoring System against results obtained with a laboratory-based comparator method (YSI Model 2300 STAT PLUS glucose analyzer). The glucose concentrations in the samples ranged from 55 to 467 mg/dL, as measured by the YSI Model 2300 STAT PLUS glucose analyzer. Results are summarized in the tables below:

Glucose Concentrations < 75mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	Within ±20mg/dL
8/9 (88.89%)	9/9 (100%)	9/9 (100%)	9/9 (100%)
Glucose Concentrations ≥ 75mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
236/362 (65.19%)	339/362 (93.65%)	357/362 (98.62%)	359/362 (99.17%)
Results from all glucose concentrations combined			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
241/371 (64.96%)	347/371 (93.53%)	366/371 (98.65%)	368/371 (99.19%)

   Linear regression of the data produced a slope of 1.030, an intercept of 0.071, and an r value of 0.9811.

   At the end of the lay-user study, each participant was asked to complete a usability questionnaire regarding ease of understanding of information in the user manual and the ease of use when performing a blood glucose test. From the sponsor's analysis of the questionnaire responses, the participants overall were satisfied with the ease of operation by

following the instructions for use in the User's Manual and the overall performance of the Contour® next GEN Blood Glucose Monitoring System.

Readability: A Flesch-Kincaid Grade Level assessment was conducted on the Contour® next GEN User Guide, Contour® next Test Strips and Contour® next Quick Start Guide and the results demonstrated that the labeling was written at lower than 8th grade level.

Accuracy at Extreme Glucose Study:

An additional study was conducted to assess the accuracy of the Contour® next GEN system at the extreme low and high ends of the claimed measurement range using 120 capillary whole blood samples with glucose concentrations below 80 mg/dL, and 128 samples greater than 250 mg/dL. Samples were altered by spiking or glycolysis in order to obtain the appropriate glucose concentrations. Samples were tested with the Contour® next GEN system with test strips from 3 lots and compared to the results obtained on YSI 2300 analyzer. The glucose concentrations in the samples ranged from 23 - 77 mg/dL on the lower end and 255 - 592 mg/dL on the higher end, as measured by the YSI 2300. Results from one representative lot are summarized below:

Contour next GEN system accuracy results for glucose <80 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
87/120 (72.5%)	114/120 (95.0%)	120/120 (100.0%)	120/120 (100.0%)
Contour next GEN system accuracy results for glucose >250 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
111/128 (86.7%)	127/128 (99.2%)	128/128 (100.0%)	128/128 (100.0%)

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The sponsor states the following in the labeling:

Nondiabetic plasma glucose concentrations should be less than 100 mg/dL in the fasting state and less than 140 mg/dL in the post-prandial state (after a meal). You should consult with your health care professional for glucose values specific to your needs.

American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of medical care in diabetes—2020. Diabetes Care. 2020;43(supplement 1):S14–S31.

F Other Supportive Instrument Performance Characteristics Data:

1. Hematocrit study: To evaluate the effect of hematocrit on the Contour® next GEN Blood Glucose Monitoring System, the sponsor analyzed venous whole blood samples at hematocrit levels of 20, 25, 30, 35, 42, 45, 50, 55, and 60% ± 2%. Each hematocrit level was adjusted to achieve five glucose levels of approximately 40, 70, 130, 200, and 350 mg/dL. Three strip lots and 24 meters were used to collect data for each hematocrit level and glucose level (n=24 per lot per hematocrit per glucose level). The percent biases relative to the comparator method demonstrated were acceptable to support the claimed hematocrit range of 20 to 55%.

2. The sponsor performed a study to evaluate the claimed minimum sample volume of 0.6 µL. Venous whole blood samples were adjusted to approximately 55, 110, 220, and 525 mg/dL. Each sample was analyzed with a sample size of 0.45, 0.50, 0.55, 0.60, and 0.70 µL using three strip lots and 10 Contour® Next meters. Results support the sponsor's minimum claimed sample volume of 0.6 µL.

3. Operating Conditions Study: The effect of operating temperatures and relative humidity on the performance of the Contour® next GEN Blood Glucose Monitoring System was evaluated using venous whole blood samples adjusted to approximately 40, 120, 350, and 525 mg/dL. Testing was conducted under the following temperature and relative humidity (RH) combinations: 5°C / 10% RH low temperature, low humidity); 5°C / 93% RH (low temperature, high humidity); 45°C / 10% RH (high temperature, low humidity); 45°C / 93% RH (high temperature, high humidity). Glucose results obtained under these conditions was collected using 15 Contour® Next meters and three lots of test strips and results were compared to the nominal condition (25°C / 50% RH). The study results support the claimed operating conditions of 5° to 45°C (41°F to 113°F) with relative humidity of 10% to 93%.

4. Altitude Study: To evaluate the effect of altitude, a study was conducted using venous whole blood samples adjusted to four concentration levels of glucose ranging from 47-408 mg/dL. Samples were placed under conditions to simulate altitude condition from 443 feet (sea level) to 20,674 feet. Each blood sample was tested using six meters with two lots of test strips. The values obtained at simulated altitudes were compared with the values obtained at the nominal condition. The results demonstrated acceptable bias to the nominal condition to support the claim in the labeling that glucose measurement performance is maintained at altitudes up to 20,674 feet.

5. Flex Studies: Sample perturbation, testing with used test strips, drop, vibration and shipping testing was completed. The testing performed demonstrated that the device is robust to intermittent sampling, sample perturbation, drop/shock, and vibration, and that an error message is returned to the user if a used test strip is inserted into the meter.

6. The sponsor provided documentation certifying that electrostatic discharge, electromagnetic interference, electrical safety, and electromagnetic compatibility (EMC) testing had been performed and the system was found to be compliant.

7. Intermittent Sampling (2nd chance testing): The Contour® next GEN Blood Glucose Monitoring System allows the user to reapply the blood sample within 60 seconds if the initial sample is insufficient to fill the test chamber. To evaluate this, the sponsor performed a study using blood samples adjusted to glucose concentrations of 60, 110, and 220 mg/dL.

Each of the three levels was tested at a hematocrit of 20, 42, and 55 for a total of nine distinct glucose/hematocrit combinations using 10 meters. The study evaluated meter performance with different initial volumes and different delay times before additional blood was added. The results were compared to the nominal condition of 0.6 µL of blood applied and the results support that accurate results are obtained with intermittent sampling.

8. Infection Control Studies: The Contour® next GEN Blood Glucose Monitoring System is intended for single patient use only. Disinfection efficacy studies were performed on the meter materials by an outside commercial laboratory, demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant Clorox Healthcare® Bleach Germicidal Wipes (EPA Registration Number 67619-12). Robustness studies were also performed by the sponsor using the Contour® Next Blood Glucose Monitoring System demonstrating that there was no change in the performance of the system or in the external materials of the meter after 260 cycles of cleaning and disinfection using the chosen disinfectant. The robustness studies were designed to simulate cleaning and disinfecting over the 5-year single-patient use life of the meter. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

9. Test Strip Lot Release Protocol: Glucose test strip lot release protocols and criteria were reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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