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

## I Background Information:

### A 510(k) Number

K231679

### B Applicant

Ascensia Diabetes Care

### C Proprietary and Established Names

CONTOUR® PLUS BLUE 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 fingertip

### 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® PLUS BLUE Blood Glucose Monitoring System consists of the CONTOUR® PLUS BLUE meter, the CONTOUR® PLUS blood glucose test strips and the Contour® Diabetes app.

The CONTOUR® PLUS BLUE 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® PLUS BLUE Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The CONTOUR® PLUS BLUE 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® PLUS BLUE Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. The CONTOUR® PLUS blood glucose test strips are for use with the CONTOUR® PLUS BLUE meter to quantitatively measure glucose in fresh capillary whole blood drawn from the fingertips.

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 PLUS BLUE blood glucose meter

## IV Device/System Characteristics:

**A Device Description:**

The CONTOUR® PLUS BLUE Blood Glucose Monitoring System consists of the CONTOUR® PLUS BLUE blood glucose meter, CONTOUR® PLUS blood glucose test strips and the CONTOUR® Diabetes App. The CONTOUR® PLUS control solution (Level 1 and Level 2) and the Microlet® NEXT lancing device and MICROLET®lancets (K220633) are to be used with the system and are sold separately. The CONTOUR® Diabetes App (previously cleared for use with the predicate CONTOUR® NEXT GEN Blood Glucose Monitoring System, k193407) is used as an optional display for results obtained with the subject device and may be used to change the CONTOUR® PLUS BLUE blood glucose meter settings.

## B Principle of Operation:

The Contour® PLUS BLUE Blood Glucose Monitoring System measures the amount of glucose in whole blood quantitatively using fresh capillary whole blood from the fingertip and displays plasma equivalent results. 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 the meter's display screen and may be used to transmit glucose values and associated data wirelessly via Bluetooth Low Energy technology to and the Contour® Diabetes App.

## C Instrument Description Information:

1. Instrument Name:

   CONTOUR® PLUS BLUE blood glucose meter

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 tested immediately upon collection.

4. Calibration:

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

5. Quality Control:

   Two levels of glucose control solutions are available for use with the CONTOUR® PLUS PLUS BLUE Blood Glucose Monitoring System which are used as a quality control check to ensure the customer that their CONTOUR® PLUS BLUE system is working properly. The CONTOUR® PLUS BLUE meter recognizes and distinguishes the control material from patient specimens automatically.

Recommendations on when to test with control solutions are provided in the labeling. Acceptable ranges for each level of control solution are printed on the test strip bottle packaging. If controls solutions fall outside the printed ranges the labeling instructs the customer to not use the system until the issue has been resolved and provides customer service contact details for support, as needed. The control test results are not included in the meter Logbook and are kept separate from the patient glucose averaging features such as blood glucose averages.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

## V Substantial Equivalence Information:

### A Predicate Device Name(s):
Contour® next GEN Blood Glucose Monitoring System

### B Predicate 510(k) Number(s):
K193407

### C Comparison with Predicate(s):

| **Device & Predicate Device(s):** | K231679 | K193407 |
|---|---|---|
| Device Trade Name | CONTOUR® PLUS BLUE Blood Glucose Monitoring System | CONTOUR® NEXT GEN Blood Glucose Monitoring System |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | Quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips. This 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 | Same |
| Test Strip Chemistry | FAD-GDH | Same |

| | | |
|---|---|---|
| Alternate Site Testing (AST) | No | Same |
| Glucose Range | 20 – 600 mg/dL | Same |
| **General Device Characteristic Differences** | | |
| Test Strip | Contour® Plus | Contour® Next |
| Sample Re-Application | 30 seconds re-application time | 60 seconds re-application time |

## VI Standards/Guidance Documents Referenced:

IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part1: General Requirements.

IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software – Software life cycle processes-79

FDA Guidance: Self Monitoring Blood Glucose Test Systems for Over-the-Counter Use issued on September 29, 2020

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:

*Within-Run Precision Evaluation:*
Within-run precision studies were performed using venous whole blood samples adjusted to 5 glucose concentration levels (ranges from 51-110, 111-150, 151-250 and 251-400 mg/dL). Each sample was tested in replicates of 10 with 3 lots of test strips and 10 meters for a total of 300 tests per glucose level. Results are summarized below:

| Glucose Level (mg/dL) | Strip Lot | N | Mean (mg/dL) | SD (mg/dL) | %CV |
|---|---|---|---|---|---|
| 30 to 50 | 1 | 100 | 39.3 | 1.4 | 3.5 |
| | 2 | 100 | 36.2 | 1.2 | 3.3 |
| | 3 | 100 | 38.1 | 1.2 | 3.3 |
| | Combined | 300 | 37.9 | 1.3 | 3.4 |
| 51 to 110 | 1 | 100 | 78.6 | 1.1 | 1.4 |
| | 2 | 100 | 76.5 | 1.2 | 1.6 |
| | 3 | 100 | 74.9 | 1.3 | 1.7 |

| Glucose Level (mg/dL) | Strip Lot | N | Mean (mg/dL) | SD (mg/dL) | %CV |
|---|---|---|---|---|---|
| | Combined | 300 | 76.7 | 1.2 | 1.6 |
| 111 to 150 | 1 | 100 | 136.0 | 2.3 | 1.7 |
| | 2 | 100 | 131.9 | 1.9 | 1.4 |
| | 3 | 100 | 130.0 | 1.3 | 1.0 |
| | Combined | 300 | 132.6 | 1.9 | 1.4 |
| 151 to 250 | 1 | 100 | 204.6 | 2.6 | 1.3 |
| | 2 | 100 | 198.2 | 4.3 | 2.2 |
| | 3 | 100 | 200.1 | 3.6 | 1.8 |
| | Combined | 300 | 200.9 | 3.6 | 1.8 |
| 251 to 400 | 1 | 100 | 339.3 | 7.7 | 2.3 |
| | 2 | 100 | 332.3 | 6.9 | 2.1 |
| | 3 | 100 | 331.1 | 5.2 | 1.6 |
| | Combined | 300 | 334.2 | 6.7 | 2.0 |

*Intermediate precision:*
Intermediate (between run) precision was evaluated using 5 levels of glucose control solutions (30-50, 51-110, 111-150, 151-250 and 251-400 mg/dL) with 3 test strip lots and 10 meters. Each control solution level was measured once a day for 10 days with each meter and test strip lot, for a total of 300 replicates per control solution level. Results are summarized below:

| Glucose Level (mg/dL) | Strip Lot | N | Mean (mg/dL) | SD (mg/dL) | %CV |
|---|---|---|---|---|---|
| 30 to 50 | 1 | 100 | 42.9 | 0.5 | 1.2 |
| | 2 | 100 | 42.5 | 0.6 | 1.5 |
| | 3 | 100 | 42.6 | 0.7 | 1.6 |
| | Combined | 300 | 42.7 | 0.6 | 1.4 |
| 51 to 110 | 1 | 100 | 83.9 | 1.0 | 1.1 |
| | 2 | 100 | 83.7 | 0.9 | 1.1 |
| | 3 | 100 | 84.7 | 1.2 | 1.4 |
| | Combined | 300 | 84.1 | 1.0 | 1.2 |
| 111 to 150 | 1 | 100 | 128.1 | 1.3 | 1.0 |
| | 2 | 100 | 127.3 | 1.7 | 1.4 |
| | 3 | 100 | 127.7 | 1.6 | 1.3 |
| | Combined | 300 | 127.7 | 1.6 | 1.2 |
| 151 to 250 | 1 | 100 | 221.6 | 2.5 | 1.1 |
| | 2 | 100 | 221.6 | 3.0 | 1.3 |
| | 3 | 100 | 222.5 | 3.2 | 1.5 |
| | Combined | 300 | 221.9 | 2.9 | 1.3 |
| 251 to 400 | 1 | 100 | 380.5 | 6.3 | 1.6 |
| | 2 | 100 | 378.1 | 6.6 | 1.7 |
| | 3 | 100 | 378.4 | 6.4 | 1.7 |
| | Combined | 300 | 379.0 | 6.4 | 1.7 |

2. Linearity:

The linearity of the glucose measurement was evaluated using venous whole blood samples adjusted to 14 glucose levels ranging from 10 to 615 mg/dL (10, 20, 40, 80, 140, 200, 260, 320, 380, 440, 500, 560, 600 and 615 mg/dL as measured by comparator method YSI 2300 Analyzer) with 3 lots of test strips. The results of linear regression analysis are summarized below:

| Test Strip Lot # | Slope | y-intercept | $R^2$-value |
|---|---|---|---|
| Lot 1 | 1.00 | 0.45 | 0.9989 |
| Lot 2 | 1.00 | 1.01 | 0.9986 |
| Lot 3 | 0.99 | 1.23 | 0.9984 |
| Combined | 1.00 | 0.90 | 0.9985 |

The results of the study support the sponsor's claimed glucose measuring range of 20-600 mg/dL. If a sample result is less than 20 mg/dL glucose, the result is flagged by the meter as "Lo". If a sample result exceeds 600 mg/dL glucose, the result is flagged by the meter as "Hi". The "Lo" and "Hi" functions were validated by the sponsor and were demonstrated to function as intended.

3. Analytical Specificity/Interference:

Studies were performed to evaluate the effect of common exogenous and endogenous compounds on the performance of the CONTOUR® PLUS BLUE Blood Glucose Monitoring System. Venous whole blood samples were prepared at glucose concentrations of approximately 60 mg/dL , 120 mg/dL and 260 mg/dL and were divided into a test pool with the potential interferent added and a control sample with no added interferent. Each was tested using three test strip lots on each of the 10 meters resulting in 30 measurements per sample. 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 (as defined by the sponsor as less than ±8% bias between the test and control samples) was observed are presented in the following table:

| Test Substance | 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 |

| Test Substance | Highest concentration tested with no significant interference (mg/dL) |
|---|---|
| Reduced Glutathione | 4.6 |
| 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 | 169 mmol/L |
| Tolbutamide | 72 |
| Tolazamide | 9 |
| Triglyceride | 1500 |
| Uric acid | 23.5 |
| Sorbitol | 0.09 |
| Xylitol | 0.09 |
| Xylose | 13.3 |
| Lactitol | 0.09 |
| Maltitol | 0.09 |
| Isomalt | 0.09 |

The sponsor has included the following information in the labeling:

Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.

4. Assay Reportable Range:

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

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

Traceability

The glucose measurement function is traceable to the National Institute of Standards and Technology (NIST) SRM 917 glucose reference material. The method comparison/lay-user study was performed using the YSI 2300 STAT Plus Glucose Analyzer as the comparator method (see section VII.C3).

Test Strip Stability

Test strip stability was assessed using accelerated and real time stability testing. Testing protocols and acceptance criteria were reviewed and found to be acceptable to support the labeling claims for the Contour Plus Blood Glucose Strips test strips. The labeling states that the test strips are stable when stored either closed or after opening of the vial until the

expiration date (up to 24 months) when stored between 41-86ºF and 10-80% relative humidity.

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® PLUS BLUE Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a lay user study with 381 lay-user participants who obtained their own fingertip capillary sample and performing a blood glucose test using only the instructions from the product labeling written in English.

The results from three test strip lots were analyzed by comparing the blood glucose results obtained by the lay users with the Contour® plus BLUE 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 native samples ranged from 40.5 to 409 mg/dL, as measured by the comparator method. Results are summarized in the tables below:

| Results from all glucose concentrations combined | | | |
|---|---|---|---|
| Within ±5% | Within ±10% | Within ±15% | Within ±20% |
| 270/381 (70.87%) | 362/381 (95.01%) | 373/381 (97.90%) | 381/381 (100%) |

Regression analysis of the data produced a slope of 1.015, an intercept of -1.2, and an r value of 0.981.

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. The results demonstrate that the participants were able to successfully perform the test, received accurate results, and found the Contour® Plus BLUE Blood Glucose Monitoring System easy to use and the labeling easy to follow.

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

Accuracy at extreme glucose concentrations

A study was conducted to assess the accuracy of Contour® PLUS BLUE Blood Glucose Monitoring System at extremely low and high glucose levels using contrived capillary blood specimens. Fifty-two (52) fingerstick specimens were glycolyzed to achieve glucose levels below 80 mg/dL, and 58 fingerstick specimens were supplemented with glucose solution to achieve levels above 250 mg/dL. All samples were tested with the Contour® PLUS BLUE Blood Glucose Monitoring System with two test strips from 3 lots and compared to the results obtained on the comparator method (YSI 2300). Results from one representative lot are summarized below:

| Contour® PLUS BLUE system accuracy results for glucose <80 mg/dL | | | |
|---|---|---|---|
| Within ±5% | Within ±10% | Within ±15% | Within ±20% |
| 44/52 (84.6%) | 51/52 (98.1%) | 52/52 (100.0%) | 52/52 (100.0%) |
| Contour® PLUS BLUE system accuracy results for glucose >250 mg/dL | | | |
| Within ±5% | Within ±10% | Within ±15% | Within ±20% |
| 52/58 (89.7%) | 58/58 (100.0%) | 58/58 (100.0%) | 58/58 (100.0%) |

## D Clinical Cut-Off:

Not applicable

## E Expected Values/Reference Range:

The sponsor states the following in the labeling:

Blood glucose values will vary depending on food intake, medication dosages, health, stress, or activity. Nondiabetic plasma glucose concentrations should be less than 100 mg/dL in the fasting state and less than 140 mg/dL in the postprandial 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® Plus BLUE Blood Glucose Monitoring System, the sponsor analyzed venous whole blood samples at hematocrit levels of 20, 25, 30, 35, 42, 50, 55, and 60%. 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 (YSI 2300) were acceptable to support the claimed hematocrit range in the labeling of 20 to 55%.

2. Sample volume
   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 and 220 mg/dL glucose. Each sample was analyzed with sample sizes of 0.45, 0.50, 0.55, 0.60, and 0.70 µL using three strip lots and 10 Contour® Plus BLUE meters. Results support the sponsor's minimum claimed sample volume of 0.6 µL. The study also demonstrated that with sample volumes below 0.6 µL, the insufficient sample volume error message (E1) functioned as intended.

3. Operating conditions study
   The effect of operating temperatures and relative humidity on the performance of the Contour® PLUS BLUE 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® PLUS BLUE glucose 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°C 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 45-400 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
   The following additional flex studies were performed with the Contour® Plus BLUE Blood Glucose Monitoring System: sample perturbation, used test strips, intermittent sampling (Second-Chance sampling), drop and sample outside measuring range. The testing demonstrated that the device is robust under these conditions.

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

7. Infection Control Studies
   The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the external materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, SaniCloth Plus Germicidal Disposable Cloths (EPA Reg # 9480-6). A robustness study was also conducted by the sponsor demonstrating that there was no change in performance or in the external materials of the meter after 260 cleaning and disinfection cycles using the SaniCloth Plus Germicidal Disposable Cloths. The robustness studies were designed to simulate 5 years of single-patient device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

8. 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.