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

I Background Information:

A 510(k) Number

K241787

B Applicant

Ascensia Diabetes Care US Inc.

C Proprietary and Established Names

CONTOUR® PLUS BLUE Blood Glucose Monitoring System, 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:

Modification to existing devices to include a new Bluetooth Low Energy (BLE) microprocessor

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.

The **Contour® NEXT GEN Blood Glucose Monitoring System** consists of the CONTOUR® next GEN meter, CONTOUR® NEXT blood glucose 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):

The following Special Conditions for Use Statements apply to both the CONTOUR® PLUS BLUE and CONTOUR® NEXT GEN blood glucose monitoring systems:

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 intended for use with 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, those dehydrated 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).
- For single-patient use only.

D Special Instrument Requirements:

CONTOUR® PLUS BLUE Blood Glucose Meter
CONTOUR® NEXT GEN Blood Glucose Meter

IV Device/System Characteristics:

A Device Description:

The CONTOUR® PLUS BLUE and CONTOUR® NEXT GEN Blood Glucose Monitoring Systems consist of a meter (CONTOUR® PLUS BLUE blood glucose meter and CONTOUR® NEXT GEN blood glucose meter respectively) and blood glucose test strips (CONTOUR® PLUS blood glucose test strips and CONTOUR® NEXT blood glucose test strips respectively). CONTOUR® NEXT control solutions (Level 1 and Level 2), MICROLET® NEXT lancing device and MICROLET® lancets (K220633), and the CONTOUR® Diabetes app are to be used with the systems and are provided separately. The CONTOUR® Diabetes App is used as an optional display for the results obtained with the subject device and may be used to change the CONTOUR® PLUS BLUE and CONTOUR® NEXT GEN meter settings.

B Principle of Operation:

The CONTOUR® PLUS BLUE and CONTOUR® NEXT GEN Blood Glucose Monitoring Systems quantitatively measures the amount of glucose in fresh capillary whole blood. The glucose measurement is achieved using an amperometric detection method by the reaction of FAD dependent glucose dehydrogenase and an electron mediator in the test strip with glucose in the sample producing 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 in plasma equivalents.

C Instrument Description Information:

1. Instrument Name:

   CONTOUR® PLUS BLUE Blood Glucose Meter
   CONTOUR® NEXT GEN Blood Glucose Meter

2. Specimen Identification:

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

3. Specimen Sampling and Handling:

   The systems are 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 meters are automatically coded and do 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 BLUE Blood Glucose Monitoring System (CONTOUR® PLUS control solution Level 1 and Level 2) and for use with the CONTOUR® NEXT GEN Blood Glucose Monitoring System (CONTOUR® NEXT control solution Level 1 and Level 2) which are used as a quality control check to ensure the customer that their CONTOUR® PLUS BLUE system is working properly. 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 vial label and foil packet. 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 CONTOUR® PLUS BLUE and CONTOUR NEXT GEN meters recognize the control solutions automatically and differentiate the control solution results from patient results. The control test results are not included in 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):

K223293

C Comparison with Predicate(s):

Device & Predicate Device(s):	K241787	K241787	K223293
Device Trade Name	CONTOUR® NEXT GEN	CONTOUR® PLUS BLUE	CONTOUR® NEXT GEN
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	Same
Glucose Range	20-600 mg/dL	Same	Same
General Device Characteristic Differences			
Bluetooth Function	New BLE microprocessor	New BLE microprocessor	Current BLE microprocessor

VI Standards/Guidance Documents Referenced:

AAMI TIR69:2017/(R)2020: “Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.”

ANSI USEMCSC C63.27-2021: “American National Standard for Evaluation of Wireless Coexistence”.

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”.

IEEE UL Std 2621.2-2022: “Standard for Wireless Diabetes Device Security: Information Security Requirements for Connected Diabetes Solutions”.

VII Performance Characteristics (if/when applicable):

The device modifications described in this submission do not impact the glucose measurement functions of the system, therefore the performance data was leveraged from previously cleared devices (K193407 for CONTOUR® NEXT GEN, and K231679 for CONTOUR® PLUS BLUE).

A Analytical Performance:

1. Precision/Reproducibility:

   Previously established in K193407 and K231679.

2. Linearity:

   Previously established in K193407 and K231679.

3. Analytical Specificity/Interference:

   Previously established in K193407 and K231679.

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

4. Assay Reportable Range:

   As previously established in K193407 and K231679, the assay reportable range is 20-600 mg/dL.

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

   Traceability to the National Institute of Standards and Technology (NIST) SRM 917 glucose reference material, as established in K193407 and K231679.

   Test strip stability protocols and acceptance criteria were previously reviewed in K193407 and K231679.

6. Detection Limit:

   Previously established in K193407 and K231679.

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:

   Not applicable.

2. Matrix Comparison:

   Not applicable. These devices are 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 previously established in K193407 and K231679.

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:

Electrical safety and EMC:
The sponsor provided documentation certifying that acceptable electrical safety and electromagnetic compatibility (EMC) testing had been performed, and both systems was found to be compliant.

Software Verification and Validation
The sponsor provided detailed information on software changes made to support the BLE modifications. The verification and validation of the software functions were reviewed and found acceptable.

Cybersecurity:
The sponsor demonstrated that cybersecurity risks associated with the modifications were adequately addressed for both systems.

Flex Studies
The following additional flex studies were performed with the modified candidate systems: vibration testing, free fall drop testing, and reliability testing. The testing demonstrated that the modified devices are robust under these conditions.

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.