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

I Background Information:

A 510(k) Number

K260545

B Applicant

Ascensia Diabetes Care

C Proprietary and Established Names

CONTOUR® PLUS BLUE Blood Glucose Monitoring System
CONTOUR® NEXT GEN Blood Glucose Monitoring System
CONTOUR® NEXT ONE 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 the CONTOUR™ DIABETES App, a component of the CONTOUR® PLUS BLUE, CONTOUR® NEXT GEN and CONTOUR® NEXT ONE Blood Glucose Monitoring Systems, to include changes to the user interface, data management, and cloud integration.

B Measurand:

Glucose in fresh capillary whole blood

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:

CONTOUR® PLUS BLUE Blood Glucose Monitoring System:
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.

CONTOUR® NEXT GEN Blood Glucose Monitoring System:
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.

CONTOUR® NEXT ONE Blood Glucose Monitoring System:
The CONTOUR® NEXT ONE Blood Glucose Monitoring System consists of the CONTOUR® NEXT ONE meter, CONTOUR® NEXT blood glucose test strips and the CONTOUR™ DIABETES App.

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.

C Special Conditions for Use Statement(s):
OTC - Over The Counter

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

- 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
- 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.

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

- Not intended for use with Alternative Site Testing (AST)

The following Special Conditions for Use Statements apply to the CONTOUR® NEXT ONE blood glucose monitoring system:

- Alternative site testing (palm) should be done only during steady state times (when glucose is not changing rapidly). Ask your health care professional if Alternative Site Testing (AST) is right for you. Do not calibrate a continuous glucose monitoring device from an AST result. Do not calculate an insulin dose based on an AST result.

D Special Instrument Requirements:

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

IV Device/System Characteristics:

A Device Description:

The CONTOUR® PLUS BLUE, CONTOUR® NEXT GEN, and CONTOUR® NEXT ONE Blood Glucose Monitoring Systems consist of a meter (CONTOUR® PLUS BLUE blood glucose meter, CONTOUR® NEXT GEN blood glucose meter, and CONTOUR® NEXT ONE blood glucose meter, respectively) and blood glucose test strips (CONTOUR® PLUS blood glucose test strips, CONTOUR® NEXT blood glucose test strips, and CONTOUR® NEXT blood glucose test strips, respectively).

Control solutions (Levels 1 and 2 of CONTOUR® PLUS or CONTOUR® NEXT control solutions), MICROLET® NEXT lancing device with MICROLET® lancets (K220633), and the CONTOUR™ DIABETES App are to be used with the systems and are provided separately.

The CONTOUR™ DIABETES App is a cloud-enabled mobile application that operates on portable devices such as a smart phone or tablet running either the Apple iOS or Android operating system. 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, CONTOUR® NEXT GEN, and CONTOUR® NEXT ONE meter settings.

B Principle of Operation:

The CONTOUR® PLUS BLUE, CONTOUR® NEXT GEN, and CONTOUR® NEXT ONE Blood Glucose Monitoring Systems quantitatively measure 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
   CONTOUR® NEXT ONE 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 each of the blood glucose monitoring system and are used as a quality control check to ensure that the systems are 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 three 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® PLUS BLUE Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

K241787

C Comparison with Predicate(s):

Device & Predicate Device(s):	K260545	K260545	K260545	K241787
Device Trade Name	**CONTOUR® NEXT ONE**	**CONTOUR® PLUS BLUE**	**CONTOUR® NEXT GEN**	**CONTOUR® PLUS BLUE**
General Device Characteristic Similarities				
Intended Use	Quantitative measurement of glucose in fresh capillary whole blood 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	Same
Wireless transmission	BLE	Same	Same	Same
General Device Characteristic Differences				
Database Storage	Removal of data storage in the app.	Removal of data storage in the app.	Removal of data storage in the app.	Data storage in the app with periodic

	Replaced with real time cloud-based data storage	Replaced with real time cloud-based data storage	Replaced with real time cloud-based data storage	backup to the cloud
Third-Party Integrations	Data Sharing via Third-Party integrations unavailable	Data Sharing via Third-Party integrations unavailable	Data Sharing via Third-Party integrations unavailable	Data Sharing via Third-Party integrations available

VI Standards/Guidance Documents Referenced:

IEC 82304 Edition 1.0 2016-10: Health software – Part 1: General requirements for product safety

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

IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION: Medical devices - Part 1: Application of usability engineering to medical devices

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

FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices", February 3, 2016

FDA Guidance, "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions", February 3, 2026

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 (K160682 for CONTOUR® NEXT ONE, K193407 for CONTOUR® NEXT GEN, and K231679 for CONTOUR® PLUS BLUE).

A Analytical Performance:

1. Precision/Reproducibility:

   Previously established in K160682, K193407, and K231679.

2. Linearity:

   Previously established in K160682, K193407, and K231679.

3. Analytical Specificity/Interference:

   Previously established in K160682, 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, K231679 and K160682, 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 previously established in K160682, K193407, and K231679.

   Test strip stability protocols and acceptance criteria were previously reviewed in K160682, K193407, and K231679 and found to be acceptable to support the open-vial and shelf-life stability claims.

6. Detection Limit:

   Previously established in K160682, 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.

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: Previously established in K160682, 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 did not change physical components of the device systems. The electrical and electromagnetic compatibility (EMC) testing performed in K160682 and K241787 are applicable to their respective device systems and devices systems were found to be compliant.

Flex Studies
The sponsor did not change physical components of the device systems. The flex studies performed in K160682, K193407, K231679 and K241787 are applicable to their respective device systems and demonstrate the devices are robust under the specified use conditions.

Software Verification and Validation

The sponsor provided detailed information on software changes made to support the modifications to the App. 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.

Usability

Usability testing was conducted in accordance with FDA Guidance, Applying Human Factors and Usability Engineering to Medical Devices, Feb 3, 2016; to ensure that the CONTOUR™ DIABETES App was easy to use by typical customers.

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.