August 27, 2026

Ascensia Diabetes Care
Shahrir Alam
Regulatory Affairs Product Manager
100 Summit Lake Dr.
Valhalla, New York 10595

Re: K260545
Trade/Device Name: CONTOUR® PLUS BLUE Blood Glucose Monitoring System, CONTOUR® NEXT GEN Blood Glucose Monitoring System, CONTOUR® NEXT ONE Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: July 24, 2026
Received: July 24, 2026

Dear Shahrir Alam:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSHUA BALSAM -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260545

Device Name
CONTOUR® PLUS BLUE Blood Glucose Monitoring System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260545

Device Name
CONTOUR® NEXT GEN Blood Glucose Monitoring System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260545

Device Name
CONTOUR® NEXT ONE Blood Glucose Monitoring System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) #: K260545

510(k) Summary

Prepared on: 2026-08-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ascensia Diabetes Care
Applicant Address	100 Summit Lake Drive Valhalla NY 10595 United States
Applicant Contact Telephone	914-266-8655
Applicant Contact	Mr. Shahrir Alam
Applicant Contact Email	shahrir.alam@ascensia.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CONTOUR® PLUS BLUE Blood Glucose Monitoring System, CONTOUR® NEXT GEN Blood Glucose Monitoring System, CONTOUR® NEXT ONE Blood Glucose Monitoring System
Common Name	Glucose test system
Classification Name	System, Test, Blood Glucose, Over The Counter
Regulation Number	862.1345
Product Code(s)	NBW

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241787	CONTOUR® PLUS BLUE Blood Glucose Monitoring System	NBW

Device Description Summary

21 CFR 807.92(a)(4)

CONTOUR® PLUS BLUE Blood Glucose Monitoring System:
The CONTOUR® PLUS BLUE meter was developed for use with CONTOUR® PLUS blood glucose test strips and CONTOUR® PLUS control solution (Level 1 and Level 2). The system utilizes amperometric biosensor technology to quantitatively measure the glucose concentration in whole blood in five seconds.

The meter provides users with the ability to set test reminders, target ranges, and meal markers. Additionally, the meter provides users with the ability to view test result trends (averages) and past results stored in the device.

The meter has a smartCOLOR® indicator to enable users to see if a glucose result is above, within, or below target range.
The CONTOUR® PLUS BLUE meter contains Bluetooth Low Energy technology built in so that the meters can communicate wirelessly to smart phones and tablets. The meter may be used to transmit glucose values and associated data via Bluetooth Low Energy technology to compatible mobile devices running Ascensia's CONTOUR™ DIABETES App.

CONTOUR® NEXT GEN Blood Glucose Monitoring System:
The CONTOUR® NEXT GEN blood glucose meter was developed for use with CONTOUR® NEXT Test Strip and CONTOUR® NEXT Control Solution (Level 1 and Level 2). The system utilizes amperometric biosensor technology to quantitatively measure the glucose concentration in whole blood in five seconds.

The meter provides users with the ability to set test reminders, target ranges, and meal markers. Additionally, the meter provides users with the ability to view test result trends (averages) and past results stored in the device. The CONTOUR® NEXT GEN meter has a smartLIGHT® indicator feature to enable users to see if a glucose result is above, within, or below target range.

The CONTOUR® NEXT GEN meter contains Bluetooth Low Energy technology built in so that the meters can communicate wirelessly to smart phones and tablets. The meter may be used to transmit glucose values and associated data via Bluetooth Low Energy technology to compatible mobile devices running Ascensia's CONTOUR™ DIABETES App.

CONTOUR® NEXT ONE Blood Glucose Monitoring System:
The CONTOUR® NEXT ONE Blood Glucose Monitoring System has been developed for use with the currently marketed CONTOUR® NEXT Test Strip and CONTOUR® NEXT Control Solution (Level 1 and Level 2). The system utilizes amperometric biosensor technology to quantitatively measure the glucose concentration in whole blood in approximately seven seconds.

The meter provides users the ability to set meal markers and view past results stored in the device. The CONTOUR® NEXT ONE meter has a smartLIGHT® indicator feature to enable users to see if a glucose result is above, within, or below target range.

The CONTOUR® NEXT ONE meter contains Bluetooth Low Energy technology built in so that the meters can communicate wirelessly to smart phones and tablets. The meter may be used to transmit glucose values and associated data via Bluetooth Low Energy technology to compatible mobile devices running Ascensia's CONTOUR™ DIABETES App.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject devices have the same intended use/indications for use as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject devices have been designed with the same intended use, operating principles, and features as their predicate. In comparison to its predicate, the subject devices are also similar in terms of functionality and performance characteristics.

The differences between the subject devices and the predicate are the changes to the user interface, data management, and cloud integration of the CONTOUR™ DIABETES App.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The CONTOUR™ DIABETES App is a mobile app component of the compatible Bluetooth-enabled CONTOUR® PLUS BLUE, CONTOUR® NEXT GEN and CONTOUR® NEXT ONE Blood Glucose Monitoring Systems. Previous analytical performance testing and clinical testing was leveraged and is applicable to the modified devices. Animal testing was not applicable to the devices in this submission. 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. The changes to the CONTOUR™ DIABETES App do not impact the performance and functionality of the compatible meter systems.

Based on the testing, the subject CONTOUR® PLUS BLUE, CONTOUR® NEXT GEN and CONTOUR® NEXT ONE Blood Glucose Monitoring Systems are substantially equivalent to the predicate CONTOUR® PLUS BLUE Blood Glucose Monitoring System.