August 27, 2024

Ascensia Diabetes Care US Inc.
Divya Munjpara
Principal Regulatory Affairs Specialist
5 Wood Hollow Road
Parsippany, New Jersey 07054

Re: K241787
Trade/Device Name: CONTOUR® PLUS BLUE Blood Glucose Monitoring System; CONTOUR® NEXT GEN Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: June 20, 2024
Received: June 21, 2024

Dear Divya Munjpara:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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.

Submission Number *(if known)*

K241787

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.

Submission Number *(if known)*

K241787

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)

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510(k) Summary for K241787

Date prepared: August 13, 2024

According to the requirements of 21 CFR 807.92, the following information is being submitted in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence.

1) Applicant/ Correspondent Contact

Divya Munjpara
Principal Regulatory Affairs Specialist
Ascensia Diabetes Care US Inc.
5 Wood Hollow Road
Parsippany, NJ 07054
Phone: 914-236-1832
Email address: divya.munjpara@ascensia.com

Consultant

Robin Martin
Regulatory Affairs Consultant
Kinetic Compliance Solutions, LLC
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2) Device name:

Trade names:
CONTOUR® NEXT GEN Blood Glucose Monitoring System
CONTOUR® PLUS BLUE Blood Glucose Monitoring System
Common name: Glucose test system
Classification name: System, Test, Blood Glucose, Over The Counter
Regulation Number: 21 CFR 862.1345
Product Code: NBW

3) Predicate device:

Primary Predicate: CONTOUR® NEXT GEN Blood Glucose Monitoring System (K223293)

Reference Device: CONTOUR® PLUS BLUE Blood Glucose Monitoring System (K231679)

4) Device Description

CONTOUR® NEXT GEN and CONTOUR® PLUS BLUE Blood Glucose Meters have Bluetooth Low Energy technology built in so that the meters can communicate wirelessly to smart phones and tablets. The CONTOUR® NEXT GEN meter uses the CONTOUR® NEXT blood glucose test strips and CONTOUR® NEXT control solution and CONTOUR® PLUS BLUE meter uses CONTOUR® PLUS blood glucose test strips and CONTOUR® PLUS control solution respectively. The meters can be connected to the CONTOUR® Diabetes app. Both the meters use two replaceable coin cell batteries. Both the meters' shape is a traditional oval form factor. The CONTOUR® NEXT GEN and

CONTOUR® PLUS BLUE meters have smartLIGHT® and smartCOLOR® indicator features respectively to see if a glucose result is above, within, or below target range.

5) Intended Use:

CONTOUR® NEXT GEN:

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® PLUS BLUE:

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.
6) Indications for Use Comparison to the Predicate:	The subject CONTOUR® NEXT GEN Blood Glucose Monitoring System and CONTOUR® PLUS BLUE Blood Glucose Monitoring System have the same intended use as the predicate device.
7) Technological Comparison to the Predicate:	The subject CONTOUR® NEXT GEN Blood Glucose Monitoring System and CONTOUR® PLUS BLUE Blood Glucose Monitoring System are substantially equivalent to its predicate CONTOUR® NEXT GEN Blood Glucose Monitoring System (K223293). The subject devices have the same intended use, measurement principle, operating principle, electrochemical reaction as its predicate. In terms of performance characteristics, the CONTOUR® NEXT GEN Blood Glucose Monitoring System is identical to the predicate device and the CONTOUR® PLUS BLUE Blood Glucose Monitoring System is identical to the reference device.

Description of Change

The proposed modification is to use an alternate Bluetooth Low Energy (BLE) microprocessor for the CONTOUR® NEXT GEN and CONTOUR® PLUS BLUE Blood Glucose Monitoring Systems.

Non-Clinical and Clinical Tests Summary

Bench testing showed that the CONTOUR® NEXT GEN Blood Glucose Monitoring System and CONTOUR® PLUS BLUE Blood Glucose Monitoring System performed as intended and met the relevant standards (ANSI IEEE C63.27-2021, IEEE UL Std 2621.2-2022, IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION), performance testing and software testing applicable to this change.

Bench testing including reliability testing, software verification and validation, and confirmation of no impacts to BGM measurement was conducted to support substantial equivalence. The modified devices also relied on previously conducted analytical testing to support substantial equivalence.

The bench testing demonstrated the measurement function was not impacted by the change and the physical system and the user interface were not impacted by the change. Therefore, usability testing and clinical testing was leveraged from the previous clearances to support substantial equivalence.

Conclusions

Based on the data and information submitted, the CONTOUR® NEXT GEN Blood Glucose Monitoring System and CONTOUR® PLUS BLUE Blood Glucose Monitoring System are substantially equivalent to the predicate device (CONTOUR® NEXT GEN Blood Glucose Monitoring System: K223293).