February 23, 2024

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

Re: K231679
Trade/Device Name: CONTOUR® PLUS BLUE Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: January 19, 2024
Received: January 22, 2024

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 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,

Leslie Landree -S

for Joshua 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231679

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.

510(k) Summary: K231679

Date prepared: February 22, 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) Submitter	Shahrir Alam Regulatory Affairs Product Manager Ascensia Diabetes Care 100 Summit Lake Drive Valhalla, NY 10595 Phone: 914-266-8655 Email address: shahrir.alam@ascensia.com
2) Device name:	Trade name: 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:	CONTOUR® NEXT GEN Blood Glucose Monitoring System (K193407)
4) Device description:	CONTOUR® PLUS BLUE Blood Glucose Monitoring System is a blood glucose monitoring system with Bluetooth Low Energy technology built in so that the meter can communicate wirelessly to smart phones and tablets. The meter uses the CONTOUR® PLUS blood glucose test strips and CONTOUR® PLUS control solution. The meter can be connected to the Contour® Diabetes app. It utilizes a similar algorithm as the one used in the CONTOUR® NEXT GEN Blood Glucose Monitoring System. It uses two replaceable coin cell batteries. The meter's shape is a traditional oval form factor and it includes an on-screen arrow that points to the color indicating if a glucose result is above, within, or below target range.

5) Intended 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.
Indications for Use Comparison:	The subject CONTOUR® PLUS BLUE Blood Glucose Monitoring System has the same intended use/indications for use as the predicate CONTOUR® NEXT GEN Blood Glucose Monitoring System.

6) Technological Comparison	The subject CONTOUR® PLUS BLUE Blood Glucose Monitoring System is substantially equivalent to its predicate CONTOUR® NEXT GEN Blood Glucose Monitoring System (K193407). The subject device has been designed with the same intended use, measurement principle, operating principle, electrochemical reaction as its predicate. In comparison to its predicate, CONTOUR® PLUS BLUE is also similar in terms of performance characteristics.

Non-Clinical and Clinical Tests Summary & Conclusions

Bench testing showed that the CONTOUR® PLUS BLUE Blood Glucose Monitoring System performed as intended and met the system specifications. Usability testing was conducted to ensure that the CONTOUR® PLUS BLUE Blood Glucose Monitoring System was easy to use by typical customers.

Clinical testing showed that the CONTOUR® PLUS BLUE Blood Glucose Monitoring System performed as intended and met the system specifications.

Based on the outcome of the nonclinical and clinical testing conducted, the CONTOUR® PLUS BLUE Blood Glucose Monitoring System is substantially equivalent to the predicate CONTOUR® NEXT GEN Blood Glucose Monitoring System (K193407).