November 18, 2022

Ascensia Diabetes Care US Inc.
Larnie James
Head of Regulatory Operations
100 Summit Lake Drive
Valhalla, NY 10595

Re: K223293
Trade/Device Name: 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: October 25, 2022
Received: October 26, 2022

Dear Larnie James:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Paula Caposino -S
Digitally signed by Paula Caposino -S
Date: 2022.11.18 17:10:53 -05'00'

Paula Caposino, Ph.D.
Acting Deputy Director
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.

510(k) Number *(if known)*
K223293

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.

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510(k) Summary k223293

Date prepared: November 18, 2022

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	Larnie James Head of Regulatory Operations Ascensia Diabetes Care US Inc 100 Summit Lake Drive Valhalla, NY 10595
2) Device name:	Trade name: Contour® NEXT GEN Blood Glucose Monitoring System Common name: Blood Glucose Monitoring System Classification name: 75 NBW; Glucose Test System, OTC Regulation Number: 21 CFR 862.1345
3) Predicate device:	CONTOUR® NEXT GEN Blood Glucose Monitoring System (k193407)
4) Device description:	CONTOUR® NEXT GEN Blood Glucose Monitoring System is a blood glucose meter with Bluetooth Low Energy technology built in so that the meter can communicate wirelessly to smart phones and tablets. The meter uses the CONTOUR® NEXT blood glucose test strips and CONTOUR® NEXT control solution. The meter can be connected to the CONTOUR® Diabetes app. It uses two replaceable CR2032 or DL2032 coin cell batteries. The meter's shape is a traditional oval form factor, and it includes an illuminated strip port with colors indicating if a glucose result is above, within, or below target.

5) Intended Use:	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.

Data demonstrating substantial equivalence

A comparison of the modified device and predicate device is provided in the table below:

Feature	**CONTOUR® NEXT GEN (Predicate device k193407)**	**CONTOUR® NEXT GEN (Subject Device)**
Meter	CONTOUR® NEXT GEN Blood Glucose Meter	Same as predicate
Meter circuit board	CONTOUR® NEXT GEN Blood Glucose Meter circuit board	Replacement or alternative meter circuit board components with same or equivalent specifications
Test strips	CONTOUR® NEXT Blood Glucose Test Strips	Same as predicate
Meter Kit outer carton box	Carton Box Dimensions: 12.065 x 6.985 x 16.670 cm	Smaller Carton Box Dimensions: 11.5 x 5.0 x 16.5 cm
Meter Kit packaging configuration	The CONTOUR®NEXT GEN Blood Glucose Monitoring System Meter Kit contents are packed alongside each other in the Meter Kit. The CONTOUR® NEXT Blood Glucose Test Strips are bottled.	The CONTOUR® NEXT GEN Blood Glucose Monitoring System Meter Kit contents are packed inside the carrying case inside the Meter Kit. The CONTOUR® NEXT Blood Glucose Test Strips are foil-packed.
User Guide	Color booklet format	Folded black and white pamphlet Minor content labeling changes

Performance Testing

Verification testing against well-established methods showed that the modified CONTOUR® NEXT GEN Blood Glucose Monitoring System, with the proposed changes outlined herein, performed as intended and met the system specifications.

The meter circuit board changes were made due to the end-of-life of components and addition of alternative suppliers.

Validation testing with the proposed black and white pamphlet User Guide demonstrated that the CONTOUR® NEXT GEN Blood Glucose Monitoring System continued to be easy to use by typical customers.

Conclusion

The modified CONTOUR® NEXT GEN Blood Glucose Monitoring System has been shown to be substantially equivalent to the predicate device, the CONTOUR® NEXT GEN Blood Glucose Monitoring System (k193407).