August 11, 2021

Ascensia Diabetes Care
Stacie Geffner-Atiya
Principal Regulatory Affairs Associate
100 Summit Lake Drive
Valhalla, New York 10595

Re: K210687
Trade/Device Name: 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: March 9, 2021
Received: March 10, 2021

Dear Stacie Geffner-Atiya:

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,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k210687

Device Name
CONTOUR® NEXT ONE Blood Glucose Monitoring System

Indications for Use *(Describe)*
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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510k Summary: K210687

Date prepared: August 11, 2021

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	Stacie Geffner-Atiya Principal Regulatory Affairs Specialist Ascensia Diabetes Care 100 Summit Lake Drive Valhalla, NY 10595
2) Device name:	Trade name: CONTOUR® NEXT ONE Blood Glucose Monitoring System Common name: Glucose Test System Classification name: NBW; Glucose Test System, OTC (21 C.F.R. Section 862.1345)
3) Predicate Device:	CONTOUR® NEXT ONE (K191286)
4) Device Description:	**CONTOUR® NEXT ONE Blood Glucose Monitoring System** is a blood glucose meter with Bluetooth Low Energy technology built in so that the meter can communicate wirelessly to a mobile smart device. The meter has a 7-segment display and icons in the display to aid the user with the features of the meter. It uses two replaceable CR2032 coin cell batteries. The associated CONTOUR Diabetes app is compatible with Apple iOS operating system and the Android operating system. The app communicates with the CONTOUR® NEXT ONE blood glucose meter using Bluetooth Low Energy wireless technology. Blood glucose test results are automatically sent to the mobile device for viewing and editing, and settings on the meter can be modified using the app. The meter remains unchanged. **The CONTOUR® NEXT Blood Glucose Test Strips** are intended for self-testing by persons with diabetes for the

quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL. The CONTOUR® NEXT Blood Glucose Test Strips are to be used with an over the counter (OTC) device utilized by lay-users with diabetes in home settings for the measurement of glucose in whole blood. There is no change in either intended use or indications for use. CONTOUR® NEXT Blood Glucose Test Strips remain the same.

The modification discussed in this Special 510K consists of the following:

1. Replacing the current CONTOUR NEXT Blood Glucose test strips in the CONTOUR NEXT ONE Blood Glucose Monitoring System packaging from CONTOUR NEXT glucose Test strips in a bottle to CONTOUR NEXT glucose test strips in foiled packaging ("Foiled Strips"). The Foiled Strips were cleared under K191286 for a retail box package. This new, alternative packaging configuration consists of the Foiled Strips (without a retail box) placed in a wallet with the other system components.

2. Replacing the current CONTOUR NEXT ONE color, booklet User Guide with a black and white pamphlet User Guide. In addition, some format and minor content labeling changes to the User Guide and Quick Reference Guide have occurred with this transformation. Please see Volume 012 for proposed labeling changes.

3. Replacing the current CONTOUR NEXT ONE Blood Glucose Monitoring System packaging with a smaller outer carton.

This modification represents an alternative labeling and packaging configuration.

5) Intended Use(s):	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 time (when glucose is not changing rapidly). The CONTOUR® NEXT Blood Glucose 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.

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

	Predicate Device	**Subject Device**
PRODUCT NAME	**CONTOUR® NEXT ONE Blood Glucose Monitoring System (K191286)**	**CONTOUR NEXT ONE Blood Glucose Monitoring System**
CHARACTERISTICS		
Meter	CONTOUR® NEXT One Meter	Same as predicate
Test strip	CONTOUR® NEXT Test Strips	Same as predicate
CONTOUR® NEXT ONE Blood Glucose Monitoring System Packaging Configuration	CONTOUR® NEXT Blood Glucose Test Strips in desiccated-lined bottle or CONTOUR® NEXT Blood Glucose Test Strips in desiccated-lined foil pouch	CONTOUR® NEXT Blood Glucose Test Strips in desiccated-lined foil pouch, place in a wallet, included in the Contour Next One

	Predicate Device	Subject Device
PRODUCT NAME	**CONTOUR® NEXT ONE Blood Glucose Monitoring System (K191286)**	**CONTOUR NEXT ONE Blood Glucose Monitoring System**
	sold separately in retail packaging.	Blood Glucose Monitoring System Packaging.
CONTOUR® NEXT ONE Blood Glucose Monitoring System Outer Carton Box	Carton Box Dimensions: 12.065 x 6.985 x 16.670 cm	Carton Box Dimensions: 11.50 x 5.00 x 16.50 cm

	Predicate Device	Subject Device
PRODUCT NAME	**CONTOUR® NEXT ONE Blood Glucose Monitoring System (K191286)**	**CONTOUR NEXT ONE Blood Glucose Monitoring System**
CHARACTERISTICS		
CONTOUR NEXT ONE Blood Glucose Monitoring System User Guide	Color Booklet Format	Folded black and white pamphlet, along with some format and minor content labeling changes have occurred with this transformation

Summary of Performance testing

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

Usability testing on the proposed black and white pamphlet User Guide was conducted to ensure that the CONTOUR® NEXT ONE Blood Glucose Monitoring System was easy to use by typical customers.

Conclusions from Performance Evaluations

Based on the outcome of the performance testing conducted, the modified CONTOUR® NEXT ONE Blood Glucose Monitoring System is substantially equivalent to the CONTOUR® NEXT ONE Blood Glucose Monitoring System (K191286).