December 23, 2021

Ascensia Diabetes Care
Colleen Burdel
Manager, Regulatory Affairs
100 Summit Lake Drive
Valhalla, New York 10595

Re: K193407
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: November 12, 2020
Received: November 13, 2020

Dear Colleen Burdel:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K193407

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 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.

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510(k) Summary

510(k) number: k193407

Date prepared: December 22, 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	Colleen Burdel Head of Product - Regulatory Affairs Ascensia Diabetes Care 100 Summit Lake Drive Valhalla, NY 10595 Phone: 914-296-2880 Email address: colleen.burdel@ascensia.com
2) Device name:	Trade name: Contour® next GEN Blood Glucose Monitoring System Common name: Blood Glucose Meter Classification name: 75 NBW; Glucose Test System, OTC
3) Predicate device:	Contour® Next ONE Blood Glucose Monitoring System (K160682)
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 test strips and Contour® next 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 ONE blood glucose meter. It uses two replaceable CR2032 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 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 detailed comparison of the modified device and predicate device is provided in the tables below:

Table of Similarities between Contour® next GEN to Contour® next ONE (k160682):

Feature	Contour® next ONE (Predicate Device; k160682)	Contour® next GEN (Subject Device)
Test strip	CONTOUR® NEXT Test strips	Same as predicate
Test strip chemistry	FAD-GDH (MLB as the mediator)	Same as predicate
Blood sample volume	0.6µL	Same as predicate
Test count-down time	5 seconds	Same as predicate
Applied voltage pattern	Multi-pulse	Same as predicate
Glucose range	20-600 mg/dL	Same as predicate
Controls	CONTOUR® NEXT Control	Same as predicate
Control solution ranges	Level 1 and 2	Same as predicate
Battery type	CR 2032	Same as predicate
Automatic calibration	Yes	Same as predicate
Enhanced error detection for test strips exposed to a reducing agent	Yes	Same as predicate
Enhanced error detection for control solution not mixed	Yes	Same as predicate
Enhanced error detection for perturbed test strips	Yes	Same as predicate
Wireless Technology	Bluetooth Low Energy to smart phones and tablets	Same as predicate
PC Connection	Micro-USB Port	Same as predicate
Test Memory	800 Results	Same as predicate
Color Indicator for Above/Below Target	Illuminated strip port, with colors, indicating whether a glucose result is above, within, or below target	Same as predicate
Sample re-application capability	60-second re-application time	Same as predicate
Compatibility with CONTOUR® DIABETES app	Yes	Same as predicate

Table of Differences between Contour® next GEN and Contour® next ONE (k160682):

Feature	Contour® next ONE (Predicate Device; k160682)	Contour® next GEN (Subject Device)
Form Factor	Rectangular Shape	Traditional Oval Shape
Algorithm	Multiple regression equations	Modified terms in the equations
Buttons	1 center button with up/down rocker button	1 'OK' button with up/down rocker button
Display	LCD with 7-segments and icons	Non-back lit, segmented display
Test Result Trends (Averages)	No	Yes
Test Reminders	No	Yes
Meal markers	Pre-meal, post-meal, fasting and no mark	Pre-meal, post-meal, and no mark
Bluetooth (Low Energy) Version	4.1	4.2

Contour® next ONE Blood Glucose Meter (Predicate Device)

Contour® next GEN Blood Glucose Meter (Subject Device)

Summary of Performance Testing

Clinical trials and bench testing showed that the Contour® next GEN Blood Glucose Monitoring System performed as intended and met the system specifications.

Usability testing was conducted to ensure that the Contour® next GEN 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 Contour® next GEN Blood Glucose Monitoring System is substantially equivalent to the predicate Contour® next ONE Blood Glucose Monitoring System (k160682).