DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 17, 2016

ASCENSIA DIABETES CARE
JENNIFER GREGORY
REGULATORY AFFAIRS MANAGER
430 S. BEIGER ST.
MISHAWAKA IN 46544

Re: K160682
Trade/Device Name: Contour Next ONE Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: November 4, 2016
Received: November 7, 2016

Dear Jennifer Gregory:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160682

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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510(k) Summary

Date prepared: November 10, 2016

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	Jennifer Gregory Regulatory Affairs Manager Ascensia Diabetes Care 430 South Beiger Street Mishawaka, IN 46544 Telephone: (574) 256-3447
2) Device name:	Trade name: CONTOUR® NEXT ONE Blood Glucose Monitoring System K160682 Common name: Blood Glucose Meter and app Classification name: 75 NBW; Glucose Test System, OTC, 75 LFR; Glucose Dehydrogenase
3) Predicate device:	CONTOUR® NEXT USB Blood Glucose Monitoring System (K150942)
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 uses the CONTOUR NEXT test strips and CONTOUR NEXT control solution. It utilizes a similar algorithm to the one used in the CONTOUR NEXT USB blood glucose meter, but this algorithm has been enhanced for even better accuracy. 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.
5) Intended Use:	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.

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 ONE to CONTOUR® NEXT USB (K150942):

Feature	CONTOUR NEXT USB (Predicate device)	CONTOUR NEXT ONE
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	
Controls	CONTOUR® NEXT Control	Same as predicate
Control solution ranges	Level 1 and 2	Same as predicate

Feature	CONTOUR NEXT USB (Predicate device)	CONTOUR NEXT ONE
Meal markers	Yes	Same as predicate
Automatic calibration	Yes	Same as predicate
Meal markers	Pre-meal, post-meal, fasting and no mark	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

Table of Differences between CONTOUR NEXT ONE and CONTOUR NEXT USB (K150942):

Feature	CONTOUR NEXT USB (Predicate device)	CONTOUR NEXT ONE
Algorithm	Multiple regression equations	Modified terms in the equations for improved accuracy
Wireless technology	No wireless communication	Bluetooth Low Energy to smart phones and tablets
PC connection	USB port	Micro-USB port
Display	Graphical OLED with text	LCD with 7-segments and icons
Color Indicator for Above/Below Target	Color display	Illuminated Strip Port, with colors indicating glucose result (red=below target, yellow=above target, green=in target)
Buttons	4	1 center button with up/down rocker button
Sample re-application capability	30-second re-application time	60-second re-application time
Battery type	Lithium Polymer rechargeable	CR 2032
Test memory	2000 results	800 results

CONTOUR® NEXT USB Blood Glucose

CONTOUR® NEXT ONE Blood Glucose Meter

Summary of Performance testing

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

Usability testing was conducted to ensure that the Contour Next One Blood Glucose Monitoring System was easy to use by typical customers. Usability testing was also done on the app to ensure that the app could be linked to the meter, that the applicable meter parameters could be set up, that data could be successfully transmitted from the meter to the app, and that the features of the app were easy to use and understand.

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 predicate Contour Next USB Blood Glucose Monitoring System (K150942).