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

ASCENSIA DIABETES CARE US INC.
JENNIFER GREGORY
PRINCIPAL REGULATORY AFFAIRS SPECIALIST
430 SOUTH BEIGER STREET
MISHAWAKA IN 46544

January 12, 2017

Re: K162336
Trade/Device Name: Contour Next EZ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: August 19, 2016
Received: August 22, 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)*
K162336

Device Name
Contour Next EZ Blood Glucose Monitoring System

Indications for Use *(Describe)*

The CONTOUR®NEXT EZ blood glucose monitoring system is an over the counter (OTC) device utilized for self-testing by persons with diabetes at home for the quantitative measurement of glucose in whole blood, is for single-patient use only, and should not be shared.

The system is intended for self testing outside the body (in vitro diagnostic use) and is to be used as an aid to monitor the effectiveness of diabetes control. The CONTOUR® NEXT EZ blood glucose monitoring system is indicated for use with fresh fingertip capillary whole blood samples.

The CONTOUR® NEXT EZ blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

The CONTOUR® NEXT test strips are for use with the CONTOUR® NEXT EZ blood glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date prepared: January 4, 2017

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 US Inc. 430 South Beiger Street Mishawaka, IN 46544 Telephone: (574) 256-3447 Fax: (574) 256-3519
2) Device name:	Trade name: Contour® Next EZ Blood Glucose Monitoring System K162336 Common name: Blood Glucose Test System Classification: Class II Classification name: Blood Glucose Test System, Over-the-Counter, 75 NBW and Glucose Dehydrogenase, 75 LFR (21 CFR § 862.1345)
3) Predicate device:	Contour Next EZ Blood Glucose Monitoring System (K130265))
4) Device description:	The Contour Next EZ Blood Glucose Meter consists of a small handheld blood glucose meter that utilizes dry reagent test strips for the measurement of glucose in capillary whole blood by persons with diabetes. Liquid control solution is used to check the performance of the system. The meter, together with the test strips and control solutions, is referred to as the Contour Next EZ Blood Glucose Monitoring System. The chemical principle utilized for both the predicate and modified devices is based on measurement of electrical current caused by the reaction of glucose in the blood with chemicals on the reagent strip. The blood sample is drawn into the tip of the reagent strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) enzyme on the reagent strip. The electrons generated by this reaction are shuttled to an electrode by a mediator chemical, producing a current that is proportional to the glucose in the sample. After a fixed reaction time, the glucose concentration in the sample is calculated and displayed.
5) Intended Use:	The CONTOUR®NEXT EZ blood glucose monitoring system is an over the counter (OTC) device utilized for self-testing by persons with diabetes at home for the quantitative measurement of glucose in whole blood, is for single-patient use only, and should not be shared. The system is intended for self-testing outside the body (in vitro

diagnostic use) and is to be used as an aid to monitor the effectiveness of diabetes control. The CONTOUR® NEXT EZ blood glucose monitoring system is indicated for use with fresh fingertip capillary whole blood samples.

The CONTOUR® NEXT EZ blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

The CONTOUR® NEXT test strips are for use with the CONTOUR® NEXT EZ blood glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

Data demonstrating substantial equivalence

The Contour Next EZ Blood Glucose Meter consists of a small handheld blood glucose meter that is substantially equivalent to the predicate device, the Contour Next EZ Blood Glucose Meter (K130265). The modified and predicate devices use the same glucose calculation algorithm. Both devices also use dry reagent test strips for the measurement of glucose in capillary whole blood by persons with diabetes and liquid controls to check the performance of the system. The same Contour Next test strips and Contour Next control solutions are used by both the modified and predicate devices.

A detailed comparison of the characteristics featured between the modified and predicate devices is provided in the tables on the following pages:

Modified Device
(Contour Next EZ meter)

Predicate Device
(Contour Next EZ meter)

Summary of the Technological Characteristics of the Modified Device Compared to Predicate		
SIMILARITIES to Predicate		
Characteristic	**Predicate** **Contour Next EZ**(K130265)	**Contour Next EZ (K162336)** **(Modified Device)**
Test Strip	Contour Next Test Strips	Same as Predicate
Control Solution	Contour Next Control Solution (Level 1 and 2)	Same as Predicate
Detection Method	Amperometric	Same as Predicate
Measuring Range	20-600 mg/dL	Same as Predicate
Sample Volume	0.6 µL	Same as Predicate
Countdown time displayed	5 Seconds	Same as Predicate
Operational Buttons	2 button choice selection and menu/power button	Same as Predicate
Battery Type	Two 3-volt lithium batteries (DL2032 or CR2032)	Same as Predicate
Operating Temperature Range	41°-113° F	Same as Predicate
Operating Humidity Range	10-93% RH	Same as Predicate
Hematocrit Range	15%-65%	Same as Predicate
Meter life	5 Years	Same as Predicate
Validated Product Used for Cleaning and Disinfection	Clorox Germicidal wipes	Same as Predicate
Before and After Meal Markers	Yes, when used in advanced setting	Same as Predicate
Calibration/Coding	Autocoding (no coding for users)	Same as Predicate
Display (technology)	Segmented (LCD), Alphanumeric characters & Icons	Same as Predicate
Display Visibility	Daylight only	Same as Predicate
Communication Link to Computer	Via serial to USB cable	Same as Predicate

Summary of the Technological Characteristics of the Modified Device Compared to Predicate		
SIMILARITIES to Predicate		
Characteristic	**Predicate** **Contour Next EZ**(K130265)	**Contour Next EZ (K162336)** **(Modified Device)**
Test Results in Memory	480 Test Results	Same as Predicate
Meter Materials	Case Top/Bottom: ABS Buttons: AS	Same as Predicate

DIFFERENCES from Predicate			
Characteristic	**Predicate** **Contour Next EZ** (K130265)	**Contour Next EZ (K162336)** **(Modified Device)**	**Risk Assessment Summary**
Improved detection of test strips that may have been exposed to a chemical that can degrade the mediator	No	Yes	The error check improves the ability of the modified meter to detect exposed test strips and provide an error message instead of a high biased result.
Improved detection of un-mixed control solution	No	Yes	The error check improves the ability of the modified meter to detect un-mixed control test solutions and provide an error message instead of a high biased result.
Improved detection of sample perturbation' during a test	No	Yes	The error check improves the ability of the modified meter to detect a sample that is disturbed during the countdown period and provide an error message instead of a biased result.
Improved data down load capabilities of the meter due to the addition of specific information parameters to the communication protocol: a) The maximum number of blood glucose (BG) records that the meter can store (BGMAX) b) The total number of BG records that have ever been stored in meter (BGTOTAL) c) Get a single BG record or set of records when requested from an	No	Yes	The communication changes do not have any impact on the user interface or customer blood glucose test results.

DIFFERENCES from Predicate			
Characteristic	**Predicate** **Contour Next EZ** (K130265)	**Contour Next EZ (K162336)** **(Modified Device)**	**Risk Assessment Summary**
external application (such as a data management system) d) Get the actual number (total) BG records that the meter currently has stored when requested from an external application (such as a data management system) e) Ability to set BGTOTAL to zero (this feature is only used for internal testing)			

Summary of Performance testing

Bench testing was conducted to ensure that the error checks acted as intended and gave error messages for:

- Test strips that had been exposed to a reducing agent
- Un-mixed control test solution
- Samples that had been disturbed during the test countdown

Equivalency testing was conducted to ensure the performance of the modified and predicate meters was not statistically different.

Software verification testing was conducted to ensure that no good results were classified as errors as a result of the modifications.

Control testing was conducted to ensure that adequately mixed control solution did not generate error codes.

Conclusions from Performance Evaluations

The Contour Next EZ Blood Glucose Monitoring System is substantially equivalent in its intended use, performance, safety and effectiveness to the predicate Contour Next EZ Blood Glucose Monitoring System (K130265) based on the performance of the modified Contour Next EZ Blood Glucose Monitoring System.