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

June 24, 2016

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

Re: K160430
Trade/Device Name: Contour Next Link Wireless Blood Glucose Monitoring System
Contour Next Blood Glucose Monitoring System
Regulation Number: 21 CFR § 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: May 26, 2016
Received: May 27, 2016

Dear Ms. 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)*
K160430

Device Name
Contour Next Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Contour Next blood glucose monitoring system is an over-the-counter (OTC) device utilized by persons with diabetes in home settings for the quantitative measurement of glucose in whole blood, and 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 blood glucose monitoring system is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. Alternative site testing should be done only during steady state times (when glucose is not changing rapidly).

The system consists of a Contour Next blood glucose meter, Contour Next test strips and Contour Next control solutions.

Contour Next test strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples.

The Contour Next blood glucose monitoring system is not intended for the diagnosis or screening for diabetes mellitus and is not intended for use on neonates.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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)*
K160430

Device Name
Contour Next Link Wireless Blood Glucose Monitoring System

Indications for Use *(Describe)*

The Contour Next Link Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the quantitative measurement of glucose in whole blood, and 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 Link Wireless Blood Glucose Monitoring System is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. Alternative site testing should be done only during steady state times (when glucose is not changing rapidly).

Contour Next Test Strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples.

The Contour Next Link Wireless Blood Glucose Monitoring System is intended to be used to transmit glucose values to Medtronic MiniMed Paradigm Insulin Pumps or Medtronic MiniMed Paradigm REAL-Time Revel Insulin Pumps or Medtronic MiniMed 530G Insulin Pumps and facilitate transfer of information to Medtronic MiniMed Carelink Therapy Management Software through use of radio frequency communication.

The Contour Next Link Wireless Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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: June 21, 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 Principal Regulatory Affairs Specialist Ascensia Diabetes Care US Inc. 430 South Beiger Street Mishawaka, IN 46544 Telephone: (574) 256-3447 Fax: (574) 256-3519
2) Device names:	Trade name: Contour® Next Link Wireless Blood Glucose Monitoring System Trade name: Contour® Next Blood Glucose Monitoring System Common name: Blood Glucose Test System Classification name: Blood Glucose Test System, Over-the-Counter, 75 NBW Glucose Dehydrogenase, 75 LFR (21 CFR § 862.1345)
3) Predicate devices:	Contour Next Link Wireless Blood Glucose Monitoring System: Contour Next Link Wireless Blood Glucose Monitoring System K122370 Contour Next Blood Glucose Monitoring System: Contour Next Blood Glucose Monitoring System K121190

4) Device descriptions:

Contour Next Link Wireless Blood Glucose Meter:

The Contour Next Link Wireless 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 Link Wireless Blood Glucose Monitoring System.

The System also contains radio frequency (RF) functions for sending blood glucose results to compatible Medtronic MiniMed insulin pumps. The RF function can also serve as a pass through for data being transmitted from Medtronic MiniMed insulin pumps to Medtronic's MiniMed PC-based data management software.

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.

Contour Next Blood Glucose Meter:

The Contour Next 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 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: **Contour Next Link Wireless Blood Glucose Monitoring System:**

The Contour Next Link Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the quantitative measurement of glucose in whole blood, and 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 Link Wireless Blood Glucose Monitoring System is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. Alternative site testing should be done only during steady state times (when glucose is not changing rapidly).

Contour Next Test Strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples.

The Contour Next Link Wireless Blood Glucose Monitoring System is intended to be used to transmit glucose values to Medtronic MiniMed Paradigm Insulin Pumps or Medtronic MiniMed Paradigm REAL-Time Revel Insulin Pumps or Medtronic MiniMed 530G Insulin Pumps and facilitate transfer of information to Medtronic MiniMed Carelink Therapy Management Software through use of radio frequency communication.

The Contour Next Link Wireless Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

Contour Next Blood Glucose Monitoring System:

The Contour Next blood glucose monitoring system is an over-the-counter (OTC) device utilized by persons with diabetes in home settings for the quantitative measurement of glucose in whole blood, and 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 blood glucose monitoring system is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. Alternative site testing should be done only during steady state times (when glucose is not changing rapidly).

The system consists of a Contour Next blood glucose meter, Contour Next test strips and Contour Next control solutions.

Contour Next test strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples.

The Contour Next blood glucose monitoring system is not intended for the diagnosis or screening for diabetes mellitus and is not intended for use on neonates.

Data demonstrating substantial equivalence

Contour Next Link Wireless meter:

The Contour Next Link Wireless Blood Glucose Meter consists of a small handheld blood glucose meter that is substantially equivalent to the predicate device, the Contour Next Link Wireless Blood Glucose Meter (K122370). 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 Link Wireless meter)

Predicate Device
(Contour Next Link Wireless meter)

Summary of the Technological Characteristics of the Modified Device Compared to Predicate		
SIMILARITIES to Predicate		
Characteristic	**Predicate** **Contour Next Link Wireless** (K122370)	**Contour Next Link Wireless** **(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
Illuminated Strip Port	Yes	Same as Predicate
Operational Buttons	4	Same as Predicate
Battery Type	Rechargeable (3.4-4.2V)	Same as Predicate
Operating Temperature Range	41°-113° F	Same as Predicate

Summary of the Technological Characteristics of the Modified Device Compared to Predicate		
SIMILARITIES to Predicate		
Characteristic	**Predicate** **Contour Next Link Wireless** (K122370)	**Contour Next Link Wireless** **(Modified Device)**
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
Meal Markers	Yes	Same as Predicate
Calibration/Coding	Autocoding (no coding for users)	Same as Predicate
User Interface	Alphanumeric, Iconic, Native Language	Same as Predicate
Display (technology)	Graphical (OLED)	Same as Predicate
Display Visibility	Day and night	Same as Predicate
Communication Port	USB Interface	Same as Predicate
Communication Link to Computer	Direct USB connection or optional USB cable	Same as Predicate
Test Results in Memory	1000 Results	Same as Predicate
User Contact Materials/Surface Finish	Display/buttons: AS Top/bottom case and USB cap: PC/ABS	Same as Predicate

DIFFERENCES from Predicate			
Characteristic	**Predicate** **Contour Next Link Wireless** (K122370)	**Contour Next Link Wireless** **(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.

Contour Next meter:

The Contour Next Blood Glucose Meter consists of a small handheld blood glucose meter that is substantially equivalent to the predicate device, the Contour Next Blood Glucose Meter (K121190). 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 below and on the following pages:

Modified Device
(Contour Next meter)

Predicate Device
(Contour Next meter)

Summary of the Technological Characteristics of the Modified Device Compared to Predicate		
SIMILARITIES to Predicate		
Characteristic	**Predicate** **Contour Next** (K121190)	**Contour Next** **(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

Summary of the Technological Characteristics of the Modified Device Compared to Predicate		
SIMILARITIES to Predicate		
Characteristic	**Predicate** **Contour Next** (K121190)	**Contour Next** **(Modified Device)**
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
Meal Markers	Yes	Same as Predicate
Calibration/Coding	Autocoding (no coding for users)	Same as Predicate
Display (technology)	Graphical (LCD), Alphanumeric characters, icons and native language	Same as Predicate
Display Visibility	Day and night	Same as Predicate
Communication Link to Computer	Via micro-USB to USB cable	Same as Predicate
Test Results in Memory	800 Test Results	Same as Predicate
User Contact Materials/Surface Finish	Case Top/Bottom: PC and ABS Buttons: Silicone Rubber	Same as Predicate

DIFFERENCES from Predicate			
Characteristic	**Predicate** **Contour Next** (K121190)	**Contour Next** **(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.

Summary of Performance testing for the Contour Next Link Wireless and Contour Next meters

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

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

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

An internal user study was conducted to ensure the modifications did not impact the blood glucose result accuracy of the Contour Next Link Wireless system.

Conclusions from Performance Evaluations

The Contour Next Link Wireless Blood Glucose Meter is substantially equivalent in its intended use, performance, safety and effectiveness to the predicate Contour Next Link Wireless Blood Glucose Meter (K122370) based on the performance of the Contour Next Link Wireless Blood Glucose Monitoring System.

The Contour Next Blood Glucose Meter is substantially equivalent in its intended use, performance, safety and effectiveness to the predicate Contour Next Blood Glucose Meter (K121190) based on the performance of the Contour Next Blood Glucose Monitoring System.