November 8, 2019

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

Re: K191286

Trade/Device Name:	CONTOUR® NEXT Blood Glucose Monitoring System CONTOUR® NEXT USB Blood Glucose Monitoring System CONTOUR® NEXT ONE Blood Glucose Monitoring System CONTOUR® NEXT EZ Blood Glucose Monitoring System CONTOUR® NEXT LINK Wireless Blood Glucose Monitoring System
Regulation Number:	21 CFR 862.1345
Regulation Name:	Glucose Test System
Regulatory Class:	Class II
Product Code:	NBW
Dated:	October 10, 2019
Received:	October 11, 2019

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.
Acting 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)*
k191286

Device Name
The 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 EX 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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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

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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)*
k191286

Device Name
The 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 its 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)

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Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k191286

Device Name
The 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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k191286

Device Name
The 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 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 draw 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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k191286

Device Name
The CONTOUR® NEXT USB Blood Glucose Monitoring System

Indications for Use *(Describe)*
The CONTOUR® NEXT USB 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 consists of a CONTOUR® NEXT USB blood glucose meter, CONTOUR® NEXT test strips and CONTOUR® NEXT control solutions.

The CONTOUR® NEXT USB 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 CONTOUR® NEXT USB 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 USB Blood Glucose Monitoring System for the quantitative measurement of glucose in whole blood.

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)

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510k Summary: k191286

Date prepared: November 4, 2019

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 names: CONTOUR® NEXT Blood Glucose Monitoring System CONTOUR® NEXT USB Blood Glucose Monitoring System CONTOUR® NEXT ONE Blood Glucose Monitoring System CONTOUR® NEXT EZ Blood Glucose Monitoring System CONTOUR® NEXT LINK Wireless Blood Glucose Monitoring System Common name: Glucose Test System Classification name: NBW; Glucose Test System, OTC (21 C.F.R. Section 862.1234)
3) Predicate device:	CONTOUR® NEXT ONE Blood Glucose Monitoring Systems: CONTOUR® NEXT (K160430) CONTOUR® NEXT USB (K150942) CONTOUR® NEXT ONE (K160682) CONTOUR® NEXT EZ (K162336) CONTOUR® NEXT LINK Wireless (K160430)
4) Device description:	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 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. The strips remain the same; and the only change is the new alternative packaging.

The modification discussed in this Special 510K consists a new, alternative packaging configuration of a desiccated-lined foil pouch, with each pouch containing five individually sealed, test strips in comparison to the existing blood glucose test strips in a desiccated-lined bottle.

The CONTOUR® NEXT Blood Glucose Test Strips are for use with the following CONTOUR® NEXT Blood Glucose Monitoring Systems:

CONTOUR® NEXT
CONTOUR® NEXT USB
CONTOUR® NEXT ONE
CONTOUR® NEXT EZ
CONTOUR® NEXT LINK Wireless

5) Intended Use(s): The CONTOUR® NEXT Blood Glucose Test Strips are indicated for use with the following CONTOUR NEXT Blood Glucose Monitoring Systems:

Blood Glucose Monitor System	Indications for Use
Contour® Next	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 screning for diabetes mellitus and its not intended for use on neonates.

Blood Glucose Monitor System	Indications for Use
Contour® Next USB	The Contour® Next USB 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 consists of a Contour® Next USB blood glucose meter, Contour® Next test strips and Contour® Next control solutions. The Contour® Next USB 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 Contour® Next USB 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 USB blood glucose monitoring system for the quantitative measurement of glucose in whole blood.

Blood Glucose Monitor System	Indications for Use
Contour® Next One	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 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 draw from the fingertips or palm. The system is intended for in vitro diagnostic use only.

Blood Glucose Monitor System	Indications for Use
Contour® Next EZ	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.

Blood Glucose Monitor System	Indications for Use
Contour® Next Link Wireless	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.

Data demonstrating substantial equivalence

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

	Predicate Device	**Proposed Device**
PRODUCT NAME	**CONTOUR® NEXT Glucose Monitoring System (K160430)**	**CONTOUR® NEXT Blood Glucose Monitoring System**
CHARACTERISTICS		
Test strip	CONTOUR® NEXT Test strips	Same as predicate
Test Strip Packaging	25, 35 or 50 Test Strips in desiccated-lined bottle	Alternative package consists of a desiccated-lined foil pouch, with each pouch containing five individually sealed, test strips.

	Predicate Device	**Proposed Device**
PRODUCT NAME	**CONTOUR® NEXT USB Glucose Monitoring System (K150942)**	**CONTOUR® NEXT USB Glucose Monitoring System**
CHARACTERISTICS		
Test strip	CONTOUR® NEXT Test strips	Same as predicate
Test Strip Packaging	25, 35 or 50 Test Strips in desiccated-lined bottle	Alternative package consists of a desiccated-lined foil pouch, with each pouch containing five individually sealed, test strips.

	Predicate Device	Proposed Device
PRODUCT NAME	**CONTOUR® NEXT ONE Glucose Monitoring System (K160682)**	**CONTOUR® NEXT ONE Glucose Monitoring System**
CHARACTERISTICS		
Test strip	CONTOUR® NEXT Test strips	Same as predicate
Test Strip Packaging	25, 35 or 50 Test Strips in desiccated-lined bottle	Alternative package consists of a desiccated-lined foil pouch, with each pouch containing five individually sealed, test strips.

	Predicate Device	Proposed Device
PRODUCT NAME	**CONTOUR® NEXT EZ Glucose Monitoring System (K162336)**	**CONTOUR® NEXT EZ Glucose Monitoring System**
CHARACTERISTICS		
Test strip	CONTOUR® NEXT Test strips	Same as predicate
Test Strip Packaging	25, 35 or 50 Test Strips in desiccated-lined bottle	Alternative package consists of a desiccated-lined foil pouch, with each pouch containing five individually sealed, test strips.

	Predicate Device	Proposed Device
PRODUCT NAME	**CONTOUR® NEXT LINK Wireless Glucose Monitoring System (K160430)**	**CONTOUR® NEXT LINK Wireless Glucose Monitoring System**
CHARACTERISTICS		
Test strip	CONTOUR® NEXT Test strips	Same as predicate
Test Strip Packaging	25, 35 or 50 Test Strips in desiccated-lined bottle	Alternative package consists of a desiccated-lined foil pouch, with each pouch containing five individually sealed, test strips.

Summary of Performance testing

Verification and validation testing against well-established methods showed that the CONTOUR® NEXT test Strips with the proposed, alternative foiled packaging, performed as intended and met the system specifications.

Usability testing was conducted on the proposed foiled packaging to ensure that the packaging was easy to use and labeling understood by typical customers.

Conclusions from Performance Evaluations

Based on the outcome of the performance testing conducted, the modified CONTOUR® NEXT Blood Glucose Test Strips are substantially equivalent to the CONTOUR® NEXT test strips cleared as part of the following Blood Glucose Monitoring Systems:.

CONTOUR® NEXT
CONTOUR® NEXT USB
CONTOUR® NEXT ONE
CONTOUR® NEXT EZ
CONTOUR® NEXT LINK Wireless