



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 Contour Next EZ blood glucose monitoring system is indicated for use with fresh fingertip capillary whole blood samples. The clinical utility of this device is to aid in monitoring the effectiveness of your diabetes control program. The Contour Next EZ blood glucose monitoring system is not intended for use for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The Contour Next 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.

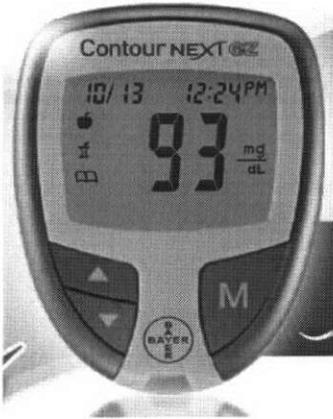
Data demonstrating substantial equivalence

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 Monitoring System (K111268). The modified device uses 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 control solutions are used by both the modified and predicate device.

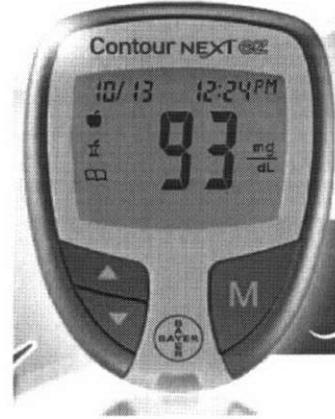
A detailed comparison of the characteristics featured between the modified and predicate devices is provided in the tables below:



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 (K111268)	Contour Next EZ (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, minimum	Same as Predicate
Countdown time displayed	5 Seconds	Same as Predicate
Illuminated Strip Port	No	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
Sound	A beep sounds when the meter	Same as Predicate



Summary of the Technological Characteristics of the Modified Device Compared to Predicate		
SIMILARITIES to Predicate		
Characteristic	Predicate Contour Next EZ (K111268)	Contour Next EZ (Modified Device)
	is turned on, a test strip is inserted, when a test strip is filled with blood, or when a test result appears on the display. Two beeps sound when the meter turns off or to indicate an error. You will hear twenty beeps when a programmed reminder sounds.	
Meter life	5 Years	Same as Predicate
Validated Product Used for Cleaning and Disinfection	Clorox Germicidal wipes	Same as Predicate
Test Reminder	Yes	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
Error Message Displays	No, but error codes and symbols are displayed and their meanings are provided in the system's User Guide	Same as Predicate
Communication Link to Computer	Via serial to USB cable	Same as Predicate
Test Results in Memory	480 Results	Same as Predicate
Meter Materials	Case Top/Bottom: ABS Buttons: AS	Same as Predicate
Before and After Meal Markers	Yes, when used in advanced setting	Same as Predicate



DIFFERENCES from Predicate			
Characteristic	Predicate Contour Next EZ (K111268)	Contour Next EZ (Modified Device)	Risk Assessment Summary
Glucose Calculation Algorithm that ensures consistent performance at low temperatures (<15°C)	No	Yes	No additional risk as a result of the modification. The risk of slightly biased results prior to the modification was low. The modification provides a more robust mathematical calculation slightly enhancing accuracy.
Improved blood detection algorithm to allow blood re-application when sensor is either severely under-filled (less than half-full) or moderately under-filled (more than half-full)	No	Yes	No additional risk as a result of the modification. Prior to the modification, the potential existed for customer dissatisfaction as underfill errors (E2) were still possible due to the limited range of performance. The modification should lead to improved customer satisfaction since results are provided instead of an error code.
Error detection algorithm to detect test strips that have been damaged by exposure to excessive moisture	No	Yes	No additional risk as a result of the modification. Prior to the modification, there is a low risk of the customer receiving biased results when test strips have been damaged by exposure to excessive moisture as a result of severe mishandling. The modification allows the meter to more frequently detect damaged test strips.

The Contour Next EZ Blood Glucose Monitoring System was evaluated according to ISO 15197:2003 using the Contour Plus Blood Glucose Monitoring System. Analytical testing included system accuracy, repeatability, linearity and intermediate precision. EMC and electrical safety of the Contour Next EZ meter was also evaluated using the Contour Plus meter.

The performance and usability of the Contour Next EZ Blood Glucose Monitoring System (including second chance sampling for under-filled test strips) was tested in the hands of intended users using the Contour Plus Blood Glucose Monitoring System.



Additional testing was performed using the modified Contour Next EZ meter to evaluate combined hematocrit and temperature effect, hematocrit effect, temperature effect, temperature and humidity combination effect, sample re-application for under-filled test strips and error detection for test strips that have been exposed to excessive moisture.

Sample volume and analytical specificity were established in K111268. Altitude testing was also included in K111268.

A summary of the test data is provided below:

Accuracy

The accuracy of the Contour Plus System was evaluated according to ISO 15197:2003 using three lots of Contour Plus test strips.

Results for glucose concentrations < 75 mg/dL:

Lot #	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
2DGHC01	26 of 26 (100%)	26 of 26 (100%)	26 of 26 (100%)
2DGHC02	25 of 26 (96.2%)	26 of 26 (100%)	26 of 26 (100%)
2DGHC03	24 of 26 (92.3%)	26 of 26 (100%)	26 of 26 (100%)
combined	75 of 78 (96.2%)	78 of 78 (100%)	78 of 78 (100%)

Results for glucose concentrations ≥ 75 mg/dL:

Lot #	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20%
2DGHC01	152 of 174 (87.4%)	173 of 174 (99.4%)	174 of 174 (100%)	174 of 174 (100%)
2DGHC02	149 of 174 (85.6%)	173 of 174 (99.4%)	174 of 174 (100%)	174 of 174 (100%)
2DGHC03	153 of 174 (87.9%)	173 of 174 (99.4%)	174 of 174 (100%)	174 of 174 (100%)
combined	454 of 522 (87.0%)	519 of 522 (99.4%)	522 of 522 (100%)	522 of 522 (100%)

Repeatability

The repeatability of the Contour Plus System was evaluated according to ISO 15197 using three lots of Contour Plus test strips across five glucose levels. The results are as follows:



Reference Glucose, mg/dL	Mean, mg/dL	Pooled Standard Deviation	Coefficient of Variation, %
42.2	44.7	1.3	2.8
79	84.6	2.1	2.5
126.4	130.6	1.9	1.5
201.3	210.0	2.8	1.3
323	333.2	4.8	1.5

Linearity

A linearity study was performed to demonstrate the analytical range of the Contour Plus assay (10-600 mg/dL). **Note: the claimed range for the Contour Next EZ meter will be 20-600 mg/dL.** The blood glucose samples that were tested ranged from 0.1 mg/dL to 692 mg/dL.

The internal acceptance criteria for accuracy was results within ± 10 mg/dL for glucose values < 100 mg/dL and results within $\pm 10\%$ for glucose values ≥ 100 mg/dL. 100% of results met the acceptance criteria

For the samples tested at 0.1 and 692 mg/dL, 100% of the tests yielded "LO" and "HI" messages as expected since those values are outside of the claimed range.

Intermediate Precision

300 control tests were performed using three lots of Contour Plus test strips and three levels of Contour Plus control solution. The internal acceptance criteria was Cp values ≥ 0.65 . All results generated Cp values > 1.0 , so the acceptance criteria was met.

EMC and Electrical Safety

The Contour Plus meter was evaluated and found to be compliant with applicable sections of IEC 62316-2-6:2005, IEC 61010-1:2001 and IEC 61010-2-101:2002

Clinical Trial

The accuracy of the Contour Plus System was evaluated in the hands of intended users according to ISO 15197:2003 using three lots of Contour Plus test strips. A total of 220 persons with diabetes were enrolled as subjects in the trial, which was conducted at two sites. The subjects ranged in age from 26 to 86 with a mean age of 60.



Results for glucose concentrations < 75 mg/dL:

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
3 of 7 (42.9%)	4 of 7 (57.1%)	7 of 7 (100%)

Results for glucose concentrations ≥ 75 mg/dL:

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20%
119 of 209 (56.9%)	186 of 209 (89.0%)	205 of 209 (98.1%)	209 of 209 (100%)

Blood Sample Re-application (Second Chance Sampling)

During the clinical trial, there were instances where users did not apply a sufficient blood sample to the Contour Plus test strip and were prompted by the Contour Plus meter to add more blood. In some cases, the attempt to apply more blood did not yield a blood glucose result and an expected E2 error was received. In the other cases, a blood glucose result was received after the additional blood sample was applied within the time allowed.

Hematocrit and Temperature Combination Study

Testing was performed using the current CONTOUR@NEXT EZ meter (K111268) and the modified Contour Next EZ meter. Three glucose concentrations and four hematocrit levels were tested at temperatures of 5, 10, 22, 35, 40 and 45°C. Acceptance criteria was met using both software versions (Bias from YSI should be less than 10 mg/dL at glucose levels below 100 mg/dL and less than 10% at higher glucose levels) However, the range of bias obtained at different hematocrits at 5 and 10°C was narrower with the modified CONTOUR@NEXT EZ meter than with the current CONTOUR@NEXT EZ meter.

Hematocrit Dependency Study

Additional testing was performed using the modified Contour Next EZ meter. Four glucose concentrations and five hematocrit levels were tested. The acceptance criteria, that bias from YSI should be less than 10 mg/dL at glucose levels below 100 mg/dL and less than 10% at higher glucose levels, was met.

Temperature Dependency Study

Testing was performed using the modified Contour Next EZ meter. Three glucose concentrations were tested at temperatures of 5, 10, 15 and 22°C. The acceptance criteria, that bias from the YSI should be less than 10 mg/dL at



glucose levels below 100 mg/dL and less than 10% at higher glucose levels, was met.

Temperature and Humidity Combination Study

The following conditions were tested using the modified Contour Next EZ meter at glucose reference levels of 20, 80, 120, 350 and 550 mg/dL:

- 5°C, 10%RH (corner)
- 5°C, 93%RH (corner)
- 25°C, 50%RH (center)
- 45°C, 10%RH (corner)
- 45°C, 93%RH (corner)

The results met the acceptance criteria of ± 10 mg/dL or ± 10 % of the reference method

Blood Sample Re-application (or Second Chance Sampling)

Re-application study conducted by lab personnel:

The improved ability of the modified Contour Next EZ meter to detect under-filled test strips was tested using the current Contour Next EZ meter (K111268) and the modified meter (K130265). The Contour Next test strips were inoculated with blood to simulate severely under-filled and moderately under-filled conditions. After the initial inoculation, additional sample was applied to the test strips. The acceptance criteria was that 95% of results fall within ± 15 mg/dL (for glucose results < 100 mg/dL) or within 15% (for glucose results ≥ 100 mg/dL) of the reference assay when the test strips were partially filled.

When the test strips were severely under-filled, the results generated by both versions of the Contour Next EZ meter met the acceptance criteria. When the test strips were moderately under-filled, the current Contour Next EZ meter generated an E2 error code 100% of the time, while the modified meter generated accurate results that met the acceptance criteria.

Re-application study done by lay users:

A study was conducted with lay users to investigate the feasibility of a proposed protocol that would increase the likelihood that patients would obtain an under-filled test strip during testing. Lay users were trained to underfill the test strips in order to generate the sample re-application prompt. The results after the sample re-application met the ISO 15197:2013 accuracy criteria with 100% of the results falling within 15% of the YSI reference glucose, indicating the method is feasible.



Lay User Re-application Data:

Data was collected from five R&D lay user studies. In these studies, there were 58 instances of under-filled test strips. The ISO 15197:2013 accuracy criteria were met with 98% of the data falling within the ± 15 mg/dL or ± 15 % of the YSI reference glucose.

Error Detection of Moisture Damaged Test Strips

Contour Next test strips were stressed by leaving the bottles open for 23 days inside a 30°C80% RH environmental chamber. This evaluation simulated severe mishandling of the test strips. After 23 days, the test strips from the open bottles (and closed bottles as a control) were tested at three glucose levels using current Contour Next EZ meters (K111268) and the modified Contour Next EZ meters (K130265). The modified Contour Next EZ meters were capable of detecting damaged test strips more frequently than the current Contour Next EZ meter and generated an E11 error code.

Conclusions from Nonclinical and Clinical Evaluations

The Contour Next EZ Blood Glucose Meter is substantially equivalent in its intended use, performance, safety and effectiveness to the predicate Contour Next EZ Blood Glucose Meter (K111268) based on the performance of the Contour Plus and Contour Next EZ Blood Glucose Monitoring Systems.



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

BAYER HEALTHCARE LLC
JENNIFER GREGORY
430 SOUTH BEIGER STREET
MISHAWAKA, IN 46544

June 23, 2014

Re: K130265

Trade/Device Name: CONTOUR® NEXT EZ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345 Glucose Test System
Regulation Name: Glucose Test System
Regulatory Class: II
Product Code: NBW, LFR
Dated: May 19, 2014
Received: June 13, 2014

Dear Ms. 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
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K130265

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 CONTOUR®NEXT EZ blood glucose monitoring system is indicated for use with fresh fingertip capillary whole blood samples. The clinical utility of this device is to aid in monitoring the effectiveness of your diabetes control program.

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

The CONTOUR®NEXT 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Stayce Beck -S

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