K112678

510(k) SUMMARY

MAR - 6 2012

Summary of 510(k) safety and effectiveness in accordance with the requirements of 21 CFR § 807.92.

Submitter Information	
Name	Bayer Healthcare LLC., Diabetes Care
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Establishment Registration Number	1826988
Name of contact person	Weiping Zhong
Date prepared	February 24 2012
Name of device	
Trade or proprietary name	Contour® NEXT EZ Blood Glucose Monitoring System
Common or usual name	Blood Glucose Monitoring System
Classification name	Glucose Test System
Classification panel	Clinical Chemistry and Clinical Toxicology
Regulation	21 CFR § 862.1345
Product Code(s)	LFR (Glucose Dehydrogenase, Glucose), NBW (System, Test, Blood Glucose, Over The Counter)
Legally marketed device(s) to which equivalence is claimed	Contour Blood Glucose Monitoring System (K062058)
Reason for 510(k) submission	Modified test strips and measurement algorithm
Device description	The Contour NEXT EZ Blood Glucose Monitoring System consists of: 1. Contour NEXT EZ Blood Glucose Meter 2. Contour NEXT Blood Glucose Test Strips 3. Contour NEXT Control Solutions
Intended use of the device	The Contour NEXT EZ Blood Glucose Monitoring System is intended to measure the glucose concentration in whole blood.

Indications for 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. The CONTOUR NEXT control solutions are aqueous glucose solutions intended for use in self-testing by people with diabetes as a quality control check.

Summary of the Technological Characteristics of the New Device Compared to Predicate

SIMILARITIES to Predicate

Characteristic	**Predicate Contour** (K062058)	**Contour NEXT EZ (Candidate Device)**
Blood Sample Volume	0.6µL	Same as predicate
Meal Markers	Yes	Same as predicate
Automatic Calibration	Yes	Same as predicate
Communication Port	Serial Interface	Same as predicate
User Interface	Alphanumeric, Iconic	Same as predicate
Display (Technology)	LCD	Same as predicate
Operational Buttons	3	Same as predicate
Battery Type	Two CR2032 (3-Volt each) (or DL2032)	Same as predicate
Displayed Countdown Time	5 seconds	Same as predicate
Detection Technology	Amperometric measurement of blood glucose	Same as predicate

Reference method	Plasma equivalent	Same as predicate
Test Strip enzyme	FAD-Glucose Dehydrogenase	Same as predicate
Calibration/Coding	Autocoding (no coding for users)	Same as predicate
DIFFERENCES from Predicate		
Characteristic	**Predicate Contour** (K062058)	**Contour NEXT EZ (Candidate Device)**
Mediator in test strip	Potassium Ferricyanide	MLB Mediator
Control Solution buffer concentration	50mM to 100 mM	22 mM
Control Solution Levels and Ranges	Low / Normal / High	Low (Level 1) / Normal (Level 2)
Applied voltage during glucose measurement	Constant	Pulsed
Hematocrit range	0%-70%	15%-65%
Measurement range	10-600mg/dL	20-600 mg/dL
Measurement Reaction time	5 seconds	7 seconds
Sample type	• Fresh fingertip capillary whole blood samples • Venous whole blood samples • Arterial whole blood samples • Neonatal blood samples	• Fresh fingertip capillary whole blood samples
Intended users	For home and professional uses	For home use, single user only
"Double Dip" function	No Inadequate sample volume results in error message	Yes System prompts for an additional application of blood in a certain time frame when a underfilled blood sample is detected

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

Characteristic	Results Summary
Accuracy	**System Accuracy Evaluation (ISO 15197 Section 7.3/7.4.1)** **Reference: 510(k) submission, Section – 001_015 System Accuracy (Book Additional Information 2)** **Protocol:** Six Contour NEXT EZ meters, three lots of test strips and 100 blood samples were tested in replicates. The first replicate (a total of three hundred data points) was analyzed. Samples were also tested in parallel on a YSI 2300 STAT PLUS glucose analyzer as reference values **Acceptance Criteria:** A minimum of 95 % of the individual glucose results shall fall within ± 15 mg/dL of the results obtained on the YSI analyzer at glucose concentrations < 75 mg/dL, and within ± 20 % at glucose concentrations ≥75 mg/dL. **Results:** All data (100%) fell within ±20% or ±15 mg/dL of the laboratory comparison method. Further, the data show an improved accuracy in that 100% of test results fall within ±10 mg/dL (<75mg/dL) and 99.2% fall within ±10% (≥ 75 mg/dL) of the laboratory comparison method.
Precision	**Repeatability (ISO 15197 Section 7.2.2)** **Reference: 510(k) submission, Section Labeled Performance Testing - Bench** **Protocol:** Venous blood was tested at five glucose concentration ranges: 30-50, 51-110, 111-150, 151-250 and 251-400mg/dL. Two operators tested one lot of test strips on 10 meters with 10 replicates per

Results within:	**±5 mg/dL**	**±10 mg/dL**	**±15 mg/dL**	
YSI Glucose <75 mg/dL	49 of 51 (96.1%)	51 of 51 (100%)	51 of 51 (100%)	
Results within:	**±5%**	**±10%**	**±15%**	**±20%**
YSI Glucose ≥ 75 mg/dL	203 of 249 (81.5%)	247 of 249 (99.2%)	249 of 249 (100%)	249 of 249 (100%)
Results within:	**±5 mg/dL or 5%**	**±10 mg/dL or 10%**	**±15 mg/dL or 15%**	**±15 mg/dL or 20%**
Total	252 of 300 (84%)	298 of 300 (99.3%)	300 of 300 (100%)	300 of 300 (100%)

meter (n=100).

Acceptance criteria: No ISO acceptance criterion established. The internal acceptance criterion was: Repeatability test must perform within the established accuracy requirements of $C_{pk} \geq 0.65$ (Cpk is difference between the mean result and the nearest limit, divided by 3 standard deviations.)

Results: The following results show that all the C_{pk} values are greater than 0.65.

Interval	Grand Mean	Pooled SD	95% CI of SD	Pooled Variance	Pooled %CV	CpK
1 (30-50)	47.3	0.8	0.7-0.9	0.6	1.7	5.9
2 (51-110)	84.2	1.1	1.0-1.2	1.3	1.3	4.6
3 (111-150)	138.5	2.1	1.9-2.3	4.3	1.5	4.1
4 (151-250)	201.5	2.6	2.4-2.9	7.0	1.3	4.5
5 (251-400)	326.3	5.0	4.6-5.5	25.1	1.5	3.7

Linearity/ assay reportable range

Reference: 510(k) submission, Section 001_003 Linearity with Truncated Data (Book Additional Information 2)

Protocol: Eight Contour NEXT EZ meters and three lots of Contour NEXT sensors (CT1, CT2, and CT3) are used to demonstrate the analytical range of the assay from 20 to 600mg/dL glucose. A fresh venous blood pool at 42% Hct was divided into eight aliquots and adjusted to plasma glucose concentrations at 21, 31, 104, 157, 312, 449, 574 and 607 mg/dL. The precision and linearity evaluation was done by collecting 30 replicate data points. Results from the Contour NEXT EZ System were compared to the YSI testing results. The data above 600mg/dL was removed from analysis.

Acceptance criteria: The acceptance criteria used for system linearity specify that (1) at least 95% of the assay results fall within ±10% for samples with glucose ≥100mg/dL or within ±10mg/dL for samples with glucose <100mg/dL relative to YSI plasma glucose values, and (2) the linear regression slope ranges from 0.93 to 1.07 and intercept ranges from -8.9 to +9.4 with correlation coefficient greater than 0.990.

Results: The linear regression analysis shows the acceptance criteria are met. Out of the 717 data points, 717 data points (100%) are within ±10mg/dL (for samples with glucose <100mg/dL) or within ±10% (for samples with glucose ≥100mg/dL) of the YSI reference. There is a good fit between the Contour NEXT EZ and the YSI testing and the slope and interception are within the specified ranges.

Regression equation	y = 0.967(x) + 1.246
95% Confidence Interval of Slope	0.964 to 0.970
95% Confidence Interval of Intercept	0.084 to 2.408
r^2	0.998
Syx	9.86

Traceability	**Reference: 510(k) submission, Section Labeled Performance Testing - Bench** Contour NEXT EZ System are referenced to the Yellow Springs Instruments Stat Plus 2300 analyzer (YSI), which is traceable to the hexokinase method developed collaboratively by the FDA, CDC, NIST and AACC. The hexokinase method is incorporated in a Bayer procedure that utilizes NIST Standard Reference Material 917, dry D-glucose. Glucose serum controls from an outside supplier were characterized by Bayer using the hexokinase method as a reference. For each day that Bayer's YSI instruments were used as the reference method, the serum controls were analyzed to ensure that the instruments were in control.
Detection limit	**Reference: 510(k) submission, Section Labeled Performance Testing - Bench** In addition to the linearity study demonstrating that accurate readings are obtained throughout the reportable range between 20 and 600 mg/dL, the system was also tested with extremely low glucose (5 mg/dL) and extremely high glucose (900, 1200, 1500, and 1800 mg/dL) to ensure that the Contour NEXT meter correctly reports "LO" and "HI" messages. Eight Contour meters (3 readings per meter) were tested with three test strip lots. All 72 readings obtained with blood adjusted to 5 mg/dL glucose reported "LO", and all 288 readings obtained with blood adjusted to 900 mg/dL and higher reported "HI". **Acceptance Criteria:** For blood with extreme glucose levels, the acceptance criterion is for the meter to display "LO" or "HI" glucose error messages. **Results:** Pass. All extremely low and extremely high samples generated "LO" or "HI" error messages as appropriate.
Analytical specificity	**Reference: 510(k) submission, Section Labeled Performance Testing - Bench** The hematocrit sensitivity of the Contour NEXT EZ System was evaluated with fresh venous blood samples ranging from 15% to 65% hematocrit. The plasma glucose concentrations were adjusted to 40 mg/dL and 550 mg/dL glucose. Twelve replicates per sample were collected on six Contour NEXT meters for each of the three lots of sensors. The results indicate that the assay bias is within 10mg/dL (when sample glucose values <100mg/dL) or 10% (when sample glucose values ≥100mg/dL) when compared to YSI references or to 40% Hct whole blood samples. The conclusion is that there is no trend of increasing assay

	imprecision or bias by increasing sample hematocrit. Other potential interference substances were tested: Acetaminophen, Ascorbic Acid, Bilirubin, Cholesterol, Creatinine HCl, Dopamine HCl, Galactose, Na Gentisate, Glutathione, Hemoglobin (g/dL), Ibuprofen (Na salt), L-Dopa, Maltose, Methyl Dopa, Na Salicylate, Tolazamide, Tolbutamide, Triglycerides, Uric Acid, Xylose Icodextrin, Caffeine, Ephedrine, and Tetracycline. It is shown that in the above substances, only xylose has a significant effect over the range tested. Therefore, in the instruction for use, it indicates "Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference."
Assay cut-off	Not applicable
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION	
Clinical study	**Reference: 510(k) submission, Section –001_004 Clinical Trials Book Additional Information 2)** **Protocol:** A clinical study was conducted at a clinical site with 115 subjects. Three lots of test strips were randomly assigned to the subjects. The clinical performance of the Contour NEXT EZ System has been demonstrated by comparing the results from the YSI lab analyzer and the HCP/User test results on the same fresh finger tip capillary blood sample. **Criteria**: ISO 15197:2003 Section 8 does not establish the clinical trials acceptance criteria. The internal acceptance criteria are that ninety-five percent (95%) of the individual glucose results shall fall within ± 15 mg/dL of the results of the manufacturer's measurement procedure at glucose concentrations < 75 mg/dL and within ± 20 % at glucose concentrations ≥ 75 mg/dL. **Results:** All (100%) Contour NEXT results meet the above accuracy requirements. Moreover, Contour NEXT results show that 100% of results fall within ±10 mg/dL at <75 mg/dL and 96.3% fall within ±10% at ≥ 75 mg/dL when tested by users on the same fresh fingertip capillary blood sample, as shown in the following table.

Results within:	±5 mg/dL	±10 mg/dL	±15 mg/dL	
YSI Glucose < 75 mg/dL	6 of 7 (85.7%)	7 of 7 (100.0%)	7 of 7 (100.0%)	
Results within:	±5%	±10%	±15%	±20%
YSI Glucose ≥ 75 mg/dL	83 of 108 (76.9%)	104 of 108 (96.3%)	107 of 108 (99.1%)	108 of 108 (100.0%)
Combined results within:	±5 mg/dL or 5%	±10 mg/dL or 10%	±15 mg/dL or 15%	±15 mg/dL or 20%
Total	89 of 115 (77.4%)	111/115 (96.5%)	114 of 115 (99.1%)	115 of 115 (100.0%)

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The performance of the Contour NEXT EZ Blood Glucose Monitoring System is substantially equivalent to the performance of the previously cleared Contour Blood Glucose Monitoring System (K062058).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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MAR - 6 2012

Re: k111268
Trade/Device Name: Contour NEXT EZ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, LFR, JJX
Dated: February 24, 2012
Received: February 27, 2012

Dear Sir/Madam:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111268

Device Name: Contour NEXT EZ Blood Glucose Monitoring System

Indications For Use:

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.

The CONTOUR®NEXT control solutions are aqueous glucose solutions intended for use in self-testing by people with diabetes as a quality control check.

Prescription Use __X__ And/Or (21 CFR Part 801 Subpart D) Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K111268