K110894

MAR 28 2012

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Bayer Healthcare, Diabetes Care
Address	430 S Beiger St Mishawaka IN 46544
Phone number	574-256-3441
Fax number	547-256-3519
Establishment Registration Number	1826988
Name of contact person	Roger Sonnenburg
Date prepared	3/26/2012
Name of device	
Trade or proprietary name	Contour® NEXT LINK Wireless Blood Glucose Meter
Common or usual name	Blood Glucose Meter
Classification name	75 LFR Glucose Dehydrogenase, Glucose
Classification panel	Clinical Chemistry and Toxicology
Regulation	21 CFR 862.1345
Product code(s)	LFR (Glucose Dehyrogenase, Glucose), NBW (System, Test, Blood Glucose, Over The Counter)
Legally marketed device(s) to which equivalence is claimed	Predicate 1 Contour USB (K091820), Predicate 2 One Touch Ultralink (K073231), Predicate 3 Care Link USB (K070438)
Reason for 510(k) submission	This submission reports a modification of the Contour USB meter (K091820). This modification includes the ability to read a new reagent strip and wireless transmission capabilities with compatible Medtronic Minimed devices
Device description	The Contour® NEXT LINK Wireless Blood Glucose Monitoring System consists of a small handheld electronic device is substantially equivalent in look and feel to the Contour® USB predicate system (K091820).The System also contains dry reagent strips and liquid controls to be used for the measurement of glucose in capillary whole blood by persons with diabetes. The System has the same automatic calibration as the predicate device. Blood glucose results are displayed on the meter window and stored in the meter's memory. The System also contains radio frequency (RF) functions for the sending of BGM

	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.
Intended use of the device	See indications for use below
Indications for use	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 measurement of glucose in whole blood, and is for single-patient use only and should not be shared. 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. The system consists of a Contour NEXT LINK wireless 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 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. 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 Paradigm® REAL-TIME Insulin Pumps or Guardian REAL-TIME 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.

Summary of the Technological Characteristics of the New Device Compared to Predicate 1 (Contour USB K091820)

Similarities to Predicate 1		
Characteristic	**Predicate 1 Contour USB K091820**	**New Device Contour NEXT LINK Wireless**
Blood sample volume	0.6µL	Same as predicate
Meal markers	Yes	Same as predicate
Automatic calibration	Yes	Same as predicate
Communication port	USB	Same as predicate
User interface	Alphanumeric, Iconic, Native Language	Same as predicate
Display (technology)	Graphical (OLED)	Same as predicate
Display visibility	Day & Night	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
Communication Link to Computer	Direct USB Connection or optional USB Cable	Same as predicate
Displayed countdown time	5 seconds	Same as predicate

Differences from Predicate 1		
Characteristic	**Predicate 1 Contour USB K091820**	**New Device Contour NEXT LINK Wireless**
Control solution ranges	Low/Normal/High	Level 1/Level 2
Control solution buffer concentration	50-100 mM	22 mM
Reagent strip compatibility	Only compatible with Contour reagent strip	Only compatible with Contour NEXT reagent strip
Total test time Contour NEXT reagent strip	N/A	7 Seconds
Software system requirements	Windows:XP,SP3,Vista SP2, 7; MAC OS 10.6.3,10.5.8; Java 1.6.0_07 or higher, High power USB port	High power USB port
Double dip function Contour NEXT reagent strip	N/A	Yes
Indications for Use	Cleared for home and professional use and fingertip, palm and forearm sampling.	Intended for home use, single patient use only fingertip and palm sampling only. RF Capability to communicate with compatible insulin pumps and act as a data pass through between insulin pumps and data management software (see Indications for Use section).
Test memory	2000 results	1000 results
User accessible data storage	Yes (500MB)	No
Data management software application on-board the meter?	Yes	No

Summary of the Technological Characteristics of the New Device Compared to Predicate 2 (One Touch Ultralink K073231)		
Similarities to Predicate 2		
Characteristic	**Predicate 2 One Touch Ultralink**	**New Device Contour NEXT LINK Wireless**
Communication	Ability to communicate with compatible insulin pump via RF	Same as predicate
Frequency	916.5 MHz	Same as predicate
Differences from Predicate 2		
Characteristic	**Predicate 2 One Touch Ultralink**	**New Device Contour NEXT LINK Wireless**
User confirmation regarding sending via RF of BGM result	RF on, RF off	RF on, RF off and RF prompt
Summary of the Technological Characteristics of the New Device Compared to Predicate 3 (Care Link USB K070438)		
Similarities to Predicate 3		
Characteristic	**Predicate 3 Care Link USB**	**New Device Contour NEXT LINK Wireless**
Pass through function	Yes	Same as predicate

PERFORMANCE DATA

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

Performance Test Summary-New Device

Characteristic	Results Summary
Precision	**Repeatability (ISO 15197 Section 7.2.2)** **Reference: 510(k) submission, Section Labeled Performance Testing Bench** **Protocol:** The repeatability of the CONTOUR NEXT LINK wireless blood glucose monitoring system was tested at glucose levels of 38, 78, 122, 204 and 326 mg/dL. Three lots of Contour Next reagent strips were tested across 10 Contour NEXT LINK wireless meters. **Acceptance Criteria:** No ISO criteria stated. Internal acceptance criteria are Cpk > 0.65 at all levels. (Cpk is difference between the mean result and the nearest limit, divided by 3 standard deviations.) **Results:** Pass, All Cpk's greater than 0.65. **Intermediate Precision (ISO 15197 Section 7.2.3)** **Reference: 510(k) submission, Section Labeled Performance Testing Bench** **Protocol:** The intermediate precision of the CONTOUR®NEXT LINK wireless blood glucose monitoring system was determined using three levels of Contour NEXT control on three Contour NEXT strip lots on 10 Contour NEXT LINK wireless meters over the course of 10 days. **Acceptance Criteria for Contour reagent strips:** No ISO criteria stated. Internal acceptance criteria are Cp > 1.0 at all levels. (Cp is the tolerance range divided by 6 standard deviations.) **Acceptance Criteria for Contour NEXT reagent strips:** Internal acceptance criteria are Cp > 1.0 at all levels **Results**: Pass, All Cp's above 1.0

<table>
<tr><td>Accuracy</td><td>
System Accuracy Evaluation (ISO 15197 Section 7.3)
Reference: 510(k) submission, Section Labeled Performance Testing Bench
Protocol: The accuracy of the CONTOUR®NEXT LINK wireless blood glucose monitoring system was assessed using 100 fresh capillary blood specimens that were collected during a fingerstick study at the Mishawaka site. The blood samples were tested using three CONTOUR® NEXT reagent lots, 10 vials per lot to yield 300 results. The reference measurement was done on a YSI™ glucose analyzer.
Acceptance Criteria: 95% ± 15 mg/dL < 75 mg/dL, 95% ± 20% ≥ 75 mg/dL

Results: Pass for Contour NEXT reagent strips.

Summary of Results for Contour Next reagent strips on Contour Next Link Wireless Meter:
<table>
<tr><td>Results within:</td><td>±5mg/dL</td><td>±10mg/dL</td><td>±15mg/dL</td><td></td></tr>
<tr><td>YSI Glucose <75 mg/dL</td><td>48 of 51 (94.1%)</td><td>51 of 51 (100%)</td><td>51 of 51 (100%)</td><td></td></tr>
<tr><td>Results within:</td><td>±5%</td><td>±10%</td><td>±15%</td><td>±20%</td></tr>
<tr><td>YSI Glucose ≥75 mg/dL</td><td>212 of 249 (85.1%)</td><td>247 of 249 (99.2%)</td><td>249 of 249 (100%)</td><td>249 of 249 (100%)</td></tr>
</table>
</td></tr>
<tr><td>Linearity/assay reportable range</td><td>
For Contour reagent strip, established in current Predicate (K091820) and previous Contour systems
Reference: 510(k) submission, Section Labeled Performance Testing Bench
Protocol: A linearity study was performed with three lots of Contour Next reagent strips. A fresh venous blood pool was divided into eight aliquots and glycolyzed at room temperature or supplemented with a glucose stock solution to produce whole blood samples with plasma across the intended glucose measuring range. The evaluation included 24 replicates on eight meters. In addition, all three reagent strip lots were tested with a blood pool adjusted to 15 mg/dL per the YSI reference, using meters with the low-end cutoff disabled.

Acceptance Criteria: Cpk ≥ 0.65 at all levels

Results: Pass, Values measured across the intended glucose measuring range
</td></tr>
<tr><td>Traceability</td><td>
The Yellow Springs Instruments Stat Plus 2300 analyzer (YSI) is traceable to the hexokinase method developed collaboratively by the FDA, CDC, NIST and AACC. The hexokinase method utilizes NIST Standard Reference Material 917b, dry D-glucose. For the YSI qualification, six-level serum controls were assayed on six different YSI analyzers over a one-month period. Each day that YSI instruments were used as the reference method, the serum controls were analyzed to ensure that the instruments were in control.

Summary of Results: Pass, Results within limits
</td></tr>
</table>

Detection limit	**Established in current Predicate (K091820) and previous Contour systems** **Reference: 510(k) submission, Section Labeled Performance Testing Bench** **Protocol:** To ensure that the performance of Contour NEXT LINK wireless blood glucose system is acceptable at glucose concentrations near the low end of the analytical range, the three clinical trial lots were evaluated with glycolyzed 42% Hct whole blood samples at approximately 10, 15, and 20mg/dL glucose. The study was done by collecting 24 replicates on eight breadboard meters which did not have the low limit set. In addition, the system was tested with blood adjusted to extremely low and extremely high glucose levels of 5, 900, 1200, 1500 and 1800 mg/dL. Eight meters were tested with a total of 72 reagent strips at 5 mg/dL, and 288 reagent strips at 900 mg/dL and above. **Acceptance Criteria:** For blood with extreme glucose levels, the acceptance criterion is for the meter to display "Low" or "High" glucose error messages. **Results:** Pass. All extremely low and extremely high samples generated "Low" or "High" error messages as appropriate.
Analytical specificity	The effect of changing hematocrit was evaluated at 15, 20, 30, 42, 55 and 65% Hct at blood glucose concentrations of 40, 90; 127 and 329 and 450 mg/dL for three reagent strip lots on 5 Contour NEXT LINK wireless meters in triplicate. A high altitude simulation study was also performed which evaluated 15, 41 and 65 % Hct at blood glucose concentrations of 40, 90 and 450 mg/dL for two reagent strip lots on 5 Contour NEXT LINK wireless meters in duplicate. The acceptance criterion was <10 mg/dL or 10% mean difference from the YSI reference values. The following interfering substances were tested: hematocrit, ascorbic acid, bilirubin, uric acid, maltose, galactose Other exogenous interfering substances were also tested, such as cholesterol, creatinine, dopamine, etc. **Summary of Results for hematocrit (Contour NEXT reagent) :** At all Hct levels, the mean difference from the reference values met the acceptance criterion. **Summary of Results for interfering substances (Contour NEXT reagent) :** Interfering substances, except for ascorbic acid, did not have a significant effect on performance. Ascorbic acid above 10 mg/dL can cause a +10% assay bias. The high end of the therapeutic range for ascorbic acid is 2 mg/dL.
Assay cut-off	Not applicable

RF of BGM result to insulin pump	**Protocol:** Electromagnetic compatibility testing was performed that included interferences; cell phone, metal detectors, EAS immunity and household emitter immunity. (N of 30 meter and pump pairs) **Acceptance criteria**: Medtronic pumps were required to successfully receive the values transmitted by the Contour NEXT LINK wireless system at a distance of 4 feet with the pump in eight different orientations. In the event there is interruption of RF Communication, any corrupted data shall be recognized and not processed. Testing was performed against RF specifications(ES9411) and product specifications (ES10255). This included the following: • Assuring the meter transmitted blood glucose values in the mg/dL to the receiving device at 4 feet at 916.5 MHz every 5 seconds for up to 12 attempts • Meter stopped transmitting after it successfully received ACK from the receiving device, and the meter stopped transmitting after 60 seconds if an ACK was not received. • Meter is capable to turn RF transmit feature On or OFF and if RF transmit feature OFF, meter will still display BG value but does not transmit BG value. • Meter has a 6 digit ID number **Results:** EMC testing with various interferences confirmed that in no case was an incorrect value accepted or displayed by the pump per RF and product specifications.
Pass through function (RF of pump data through BGM to PC based data management software when connected to PC USB port)	**Protocol:** Testing was performed that assured the Contour NEXT LINK wireless meter, when connected to a PC USB port, enabled communications between the compatible Medtronic MiniMed device and a PC for the purpose of allowing meter data and settings to be downloaded to Medtronic data management software. **Acceptance criteria**: Testing was performed against RF specifications (ES9411) and product specifications (ES10255). **Results**: Data transfer and pass-through mode testing demonstrated successful data transfer operation for the pass through mode.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical Performance Data/Information

Reference: 510(k) submission, Section Labeled Clinical Trials

Protocol for Contour NEXT LINK wireless meters using Contour NEXT reagent strips:

The Contour NEXT wireless blood glucose monitoring system clinical trial included 110 adults aged 19-86. 88% of the subjects managed their diabetes at home with insulin.

Three lots of reagent were tested in the study with each subject randomized to one lot. Each subject performed one fingerstick self test, followed by testing of the subject's blood by the study staff. Subjects also performed AST self tests on the palm. All meter results were compared to the YSI reference results.

Acceptance Criteria for Contour NEXT LINK wireless meter using Contour NEXT reagent strips:

95% of results within ±20% (≥ 75 mg/dL) or within ±15 mg/dL (< 75 mg/dL) of YSI results

Clinical trial results for Contour®Next Link Wireless System

Clinical Trial Results for Contour®Next Link Wireless - Contour®Next Strips:
Fingerstick 110 results: 110 subjects, 1 lot per subject, 3 lots overall

Results within:	**±5 mg/dL**	**±10 mg/dL**	**±15 mg/dL**	**±20 mg/dL**
YSI Glucose <75 mg/dL	8 of 8 (100%)	8 of 8 (100%)	8 of 8 (100%)	8 of 8 (100%)
Results within:	**±5%**	**±10%**	**±15%**	**±20%**
YSI Glucose ≥75 mg/dL	82 of 102 (80.4%)	101 of 102 (99.0%)	101 of 102 (99.0%)	102 of 102 (100%)
Results within:	**±5 mg/dL or 5%**	**±10 mg/dL or 10%**	**±15 mg/dL or 15%**	**±15 mg/dL or 20%**
Total	90 of 110 (81.8%)	109 of 110 (99.1%)	109 of 110 (99.1%)	110 of 110 (100%)

Clinical Trial Results for Contour®Next Link Wireless - Contour®Next Strips: AST Palm
109 results: 109 subjects, 1 lot per subject, 3 lots overall

Results within:	**±5 mg/dL**	**±10 mg/dL**	**±15 mg/dL**	**±20 mg/dL**
YSI Glucose <75 mg/dL	6 of 7 (85.7%)	7 of 7 (100%)	7 of 7 (100%)	7 of 7 (100%)
Results within:	**±5%**	**±10%**	**±15%**	**±20%**
YSI Glucose ≥75 mg/dL	61 of 102 (59.8%)	90 of 102 (88.2%)	98 of 102 (96.1%)	99 of 102 (97.1%)
Results within:	**±5 mg/dL or 5%**	**±10 mg/dL or 10%**	**±15 mg/dL or 15%**	**±15 mg/dL or 20%**
Total	67 of 109 (61.5%)	97 of 109 (89.0%)	105 of 109 (96.3%)	106 of 109 (97.3%)

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The performance of the Contour NEXT LINK Wireless Blood Glucose Monitoring System is substantially equivalent to the performance of the previously cleared Contour USB Blood Glucose Monitoring System (K091820), One Touch Ultralink (K073231) and Care Link USB (K070438).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Bayer HealthCare LLC, Diabetes Care
c/o Roger Sonnenburg
430 South Beiger St
Mishawaka, IN 46544

MAR 2 8 2012

Re: k110894
Trade Name: CONTOUR® NEXT LINK Wireless Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: LFR, NBW,JJX
Dated: March 27, 2012
Received: March 28, 2012

Dear Mr. Sonnenburg:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 K110894:

Device Name: Contour® NEXT LINK Wireless Blood Glucose Monitoring System

Indications for Use:

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 measurement of glucose in whole blood, and is for single-patient use only and should not be shared. 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. The system consists of a Contour NEXT LINK Wireless 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 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.

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 Paradigm® REAL-TIME Insulin Pumps or Guardian REAL-TIME Monitor 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.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or 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) K110894