510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k110587

B. Purpose for Submission:

Modified device (Addition of the radio frequency transmitter to the previously cleared Contour blood glucose monitoring system under k062058)

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose dehydrogenase (FAD)

E. Applicant:

Bayer HealthCare LLC, Diabetes Care

F. Proprietary and Established Names:

CONTOUR® Link Wireless Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LFR – Glucose dehydrogenase, glucose	Class II	21 CFR § 862.1345	75-Chemistry
NBW – system, test, blood glucose, over the counter	Class II	21 CFR § 862.1345	75-Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

The CONTOUR® 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® LINK Wireless Blood Glucose Monitoring System is indicated for use with fresh capillary whole blood samples drawn from the fingertip only.

CONTOUR® 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® 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 Pump.

The CONTOUR® 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.

3. Special conditions for use statement(s):

   For over-the-counter use and for prescription use.

   For single-patient use only.

   For use with capillary whole blood samples drawn from the fingertip.

   Not for neonatal use, not for screening or diagnosis of diabetes mellitus.

   May be used to transmit glucose values to compatible Medtronic MiniMed devices through use of radio frequency communication.

   Not for use on critically ill patients (e.g. those with severe hypotension or shock, hyperglycemic-hyperosmolar state, hypoxia, severe dehydration, diabetic ketoacidosis).

4. Special instrument requirements:

   Contour Link Wireless Blood Glucose Meter

I. Device Description:

The CONTOUR® Link Wireless is a blood glucose meter equipped with an RF transmission device allowing transfer of blood glucose measurements to compatible Medtronic diabetes devices.

The internal detailed design of the CONTOUR® Link Wireless meter that executes the blood glucose measurement is based on technology already established with Bayer's CONTOUR® meter. The CONTOUR® Link Wireless system also uses existing CONTOUR® test strips and control solutions from Bayer. The methods for measuring glucose, including algorithms, temperature compensation, and User interface (UI) are equivalent between the CONTOUR® Link meter and the CONTOUR® meter. Results of blood glucose tests are stored within the meter. The CONTOUR® Link Wireless system also contains an RF daughter board that allows transmission of blood glucose results to compatible Medtronic MiniMed devices.

The CONTOUR® Link Wireless Blood Glucose Monitoring System consists of the following components:

- CONTOUR® Link Wireless Blood Glucose Meter
- CONTOUR® blood glucose test strips – 10 ct (cleared in k062058)
- CONTOUR® control solutions (three levels, cleared in k062058)

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bayer's CONTOUR® Blood Glucose Monitoring System (k062058)

2. Predicate K number(s):

   k062058

3. Comparison with predicate:

Item	**Candidate device** **Bayer's Contour Link Wireless**	**Predicate device** **Bayer's Contour (**k062058)
Intended Use/Indications for Use	Same	For the quantitative measurement of glucose in whole blood.
	Over-the-counter (OTC) device used by persons with diabetes in home settings. For single patient use only.	Over-the-counter (OTC) device used by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities.
	Capillary samples only. Not for use on neonates.	For use with capillary, venous, and arterial whole blood samples and neonatal blood samples.
	Fingertip samples only.	Capillary samples may be drawn from the fingertip, palm, forearm, and in the case of neonates, the heel.

	May be used to transmit glucose values to compatible Medtronic MiniMed devices through use of radio frequency communication.	No RF capability
Hardware/software for Glucose measurement	Same	Design used in Contour meter
Detection method	Same	Amperometry
Test strip	Same	CONTOUR test strip
Test strip enzyme	Same	Glucose Dehydrogenase FAD
Controls	Same	Bayer glucose control solutions
Calibration Coding	Same	No coding by user
Test range	20 - 600 mg/dL	10-600 mg/dL
Sample volume	Same	0.6 µL
Power supply	Same	Two 3V Li battery (CR2032 or DL2032)
Memory	Same	Most recent 480 test results

K. Standard/Guidance Document Referenced (if applicable):

None were referenced.

L. Test Principle:

The CONTOUR®Link Wireless blood glucose test is based on measurement of electrical current caused by the reaction of glucose with the reagents on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and potassium ferricyanide. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed on the meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

The current device differs from the predicate in the addition of the radio frequency transmitter to the existing Contour blood glucose monitoring device. The modification does not affect the analytical function of the meter and the current device uses the same test strips and control solutions as cleared in the predicate device in k062058.

a. Precision/Reproducibility:

Within-run precision was evaluated using venous blood samples at five glucose concentration ranges: 30 – 50, 51 – 110, 111 – 150, 151 – 250 and 251 – 400 mg/dL. Three lot of test strips were tested on 10 meters with 10 replicates per meter (N=100/lot). Results are summarized below:

Within-run precision for glucose:

Lot	Glucose Level	Mean (mg/dL)	SD (mg/dL)	% CV
1	1	43.8	1.4	3.2
	2	78.4	2.6	3.4
	3	129.8	3.8	2.9
	4	192.9	4.7	2.5
	5	316.2	11.6	3.7

Lot	Glucose Level	Mean (mg/dL)	SD (mg/dL)	% CV
2	1	44.1	1.2	2.8
	2	79.2	2.7	3.4
	3	130.0	3.1	2.4
	4	194.4	5.2	2.7
	5	314.2	5.4	1.7

Lot	Glucose Level	Mean (mg/dL)	SD (mg/dL)	% CV
3	1	46.3	2.0	4.2
	2	82.1	2.2	2.6
	3	130.8	5.0	3.8
	4	195.2	4.4	2.2
	5	320.0	7.3	2.3

Between-day precision was evaluated using three levels of control solutions. One measurement was taken per meter on 10 meters over the course of 10 days using 3 lots of strips (N = 100). Results are summarized below:

Between-day precision for glucose:

Lot	Level	Mean (mg/dL)	SD (mg/dL)	%CV
1	Low	40.1	0.7	1.8
	Normal	123.8	1.8	1.5
	High	358.1	5.8	1.6
2	Low	41.4	0.8	1.9
	Normal	127.0	2.7	2.1
	High	373.4	7.1	1.9
3	Low	38.3	0.8	2.1
	Normal	119.9	1.8	1.5
	High	350.6	6.9	2.0

b. Linearity/assay reportable range:

Linearity was established in predicate submission (k062058, Bayer's CONTOUR® blood glucose monitoring system). The established linearity in the predicate device was 10-600 mg/dL. The sponsor stated that the new meter has the same hardware or software involved in the measurement of glucose. The difference between the two meters is that the new device is 4 mm thicker to accommodate the new RF transmitter. The claimed linearity for the new

device is 20-600 mg/dL due to absence of neonatal claim.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability: Traceable to NIST SRM 91, dry D-glucose.

Controls: The controls were cleared under k062058.

Stability: The controls and test strips were cleared under k062058. Stability data was presented and reviewed in k062058.

d. *Detection limit:*

See linearity section 1. b. above.

e. *Analytical specificity:*

Interference

As established in predicate k062058. The predicate data was re-evaluated and found to be acceptable.

Additional interference testing was performed on multiple levels (3) of maltose, galactose, xylose, bilirubin, acetaminophen, uric acid and ascorbic acid meeting and exceeding the maximum concentration of the substance expected to be encountered in clinical practice.

The results validate the strip labeling statements:

Strip Labeling Statements:

- Reducing substances occurring in the blood naturally (uric acid, acetaminophen) will not significantly affect results.

- Interference might occur when the values of the limiting concentrations of these compounds are greater than those listed below:
  Bilirubin >20 mg/dL
  Uric Acid >18 mg/dL
  Ascorbic Acid >30 mg/dL
  Acetaminophen >22 mg/dL
  Maltose >200 mg/dL
  Galactose >200 mg/dL

- Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause interference.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with reference method (*Contour Link Wireless versus YSI*):

Fingerstick and plasma samples from 100 diabetic subjects were included in the study. In order to fill the bins at the low and high end of the distribution, 19 samples were either glycolyzed to a lower concentration or supplemented with glucose to increase the concentration. 4 measurements were obtained for each sample using two reagent lot and two CONTOUR Link Wireless meters. Plasma samples were also tested in parallel on an YSI 2300 STAT PLUS glucose analyzer, and the result was used as the comparison value. All measurements were performed at 23°C ± 5°C.

The distribution of the sample glucose concentrations is specified in the table below.

Sample description:

Glucose Concentration (mg/dL)	Number of samples		
	Total	Fresh Capillary Blood	Manipulated Capillary Blood
< 50	5	0	5
51 - 80	15	9	6
81 - 120	20	20	0
121 - 200	30	30	0
201 - 300	15	15	0
301 - 400	10	4	6
> 400	5	3	2

The ISO 15197 Acceptance Criteria are as follows:
95% of individual glucose results shall fall within ±15mg/dL (0.83mmol/L) of reference method at glucose concentrations < 75mg/dL (4.2mmol/L) and within ± 20% at glucose concentrations ≥ 75mg/dL (4.2mmol/L).

The results are presented as follows:

Glucose < 75 mg/dL (19 samples)

Number of test result	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
76	53 of 76 (69.7%)	68 of 76 (89.5%)	75 of 76 (98.7%)

Glucose ≥ 75 mg/dL (81 Samples)

Number of test results	Within ± 5 %	Within ± 10 %	Within ± 15%	Within ± 20%
324	177 of 324 (54.6 %)	276 of 324 (85.2 %)	312 of 324 (96.3 %)	319 of 324 (98.5 %)

Summary Assessment of Accuracy (100 Samples)

Number of test results	Readings within ±15 mg/dL if <75 mg/dL, ±20% if ≥75 mg/dL
400	98.5% (394 of 400)

b. User performance study

As established in the predicate device cleared under k062058.

c. Matrix comparison:

Not applicable. Only capillary whole blood samples are acceptable matrix.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The following is stated in the labeling:
"Blood sugar values will vary depending on food intake, medication dosages, health, stress, or activity. Non diabetic plasma glucose concentrations are normally maintained within a relatively narrow 70-110 mg/dL in the fasting state. You should consult with your healthcare provider for expected glucose values specific to your

needs."

[1] Longo DL, et al.: Harrison's Principles of Internal Medicine-18th edition, 2011:3003.

N. Instrument Name:

CONTOUR® Link Wireless Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.6 uL.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___X_____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ___X_____ or No _____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X_____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the finger only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   There is no calibration required for the CONTOUR®Link Wireless Blood Glucose Meter by the user. The meter is automatically coded.

6. Quality Control:

   Glucose control solutions at three different concentrations can be used with this device. The meter automatically distinguishes control solution from blood and marks control solution tests with a check mark and excludes them from average calculations. Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the control solutions vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (User Guide, test strip package insert and control solution package insert) were written at the 8^{th} grade level.

2. Customer service is available 24/7, 365 days a year. Toll free phone number is 1-800-348-8100 for Bayer Diabetes Care customer support.

3. Temperature and humidity operating conditions were evaluated for temperatures ranging from 41^{o}F-113^{o}F (5^{o}C to 45^{o}C) and relative humidity from 10% to 93%. Protocol and acceptance criteria were provided and found to be acceptable. The results supported the Sponsor's claimed operating temperature from 41^{o}F-113^{o}F and relative humidity range from 10% to 93%.

4. EMC testing was performed on the CONTOUR® Link Wireless Blood Glucose Meter by an accredited EMC Testing Laboratory LS Research, LLC. A letter of attestation was issued to Bayer on October 12, 2007.

5. The sponsor claims that the current device can be used at altitudes up to 11,000 feet based on the study performed on the predicate meter cleared in k062058.

6. The sponsor performed hematocrit studies on five Contour® Link Wireless meters using 6 different hematocrit levels (15, 20, 25, 30, 42, 55 and 65%) across 5 glucose concentrations (40, 80, 120, 350, 500 mg/dL). At each hematocrit level, samples at various glucose concentrations were tested against the YSI method. The bias of all test results were less than 10 mg/dL (at glucose <100 mg/dL) or less than 10% (at glucose ≥100 mg/dL) compared to YSI method, therefore the sponsor claims that hematocrit between 20% to 65% does not significantly affect the glucose results.

7. Disinfection and Robustness studies:
   The device is intended for single-patient use only. Clorox® Germicidal Wipes containing 0.55% sodium hypochlorite with EPA registration # 67619-12 was validated demonstrating complete inactivation of live virus using materials used in the meter and lancing device. The sponsor also demonstrated that there

was no change in performance or in the external materials of the meter and lancing device after 260 cleaning and disinfection cycles designed to simulate cleaning and disinfection 1x per week for 5 years. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

8. The software changes related to the modified functions (Bluetooth data transmission and memory storage of up to 1000 tests) were tested and the intended functions were validated.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.