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

A. 510(k) Number:
k090628

B. Purpose for Submission:
New device

C. Measurand:
Whole blood glucose

D. Type of Test:
Whole blood glucose concentration through a quantitative amperometric assay (Glucose Dehydrogenase -FAD)

E. Applicant:
Bayer HealthCare, LLC.

F. Proprietary and Established Names:
DIDGET Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1345, Blood Glucose Test System
   21 CFR 862.1660, Quality Control Material (assayed and unassayed)

2. Classification:
   Class II
   Class I, reserved

3. Product codes:
   NBW, Blood Glucose Test System, Over-the-Counter
   LFR, Glucose Dehydrogenase, Glucose
   JJX, Single (specified) analyte controls (assayed and unassayed)

4. Panel:
   75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
   Refer to indications for use below.

2. Indication(s) for use:

The DIDGET blood glucose monitoring system (meter, strips, and controls) is intended for self-testing by people with diabetes to monitor glucose concentrations in fresh capillary whole blood samples drawn from the fingertip only. It is intended for those ages four and older, with adult supervision as needed. The DIDGET 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):
   - Not intended for diagnosis of diabetes mellitus
   - For in vitro diagnostic use only
   - Not intended for use on neonates
   - Not for use on critically ill patients, dehydrated patients, patients in shock, or hyperosmolar patients
   - Adult supervision is needed for young children

4. Special instrument requirements:
   DIDGET Blood Glucose Meter

I. Device Description:

The DIDGET Blood Glucose Monitoring System consists of DIDGET Blood Glucose Monitor, Contour Blood Glucose Test Strips, and Contour Control Solution.

DIDGET meter interfaces to Nintendo DS or DS Lite gaming system, where the user can play DIDGET -compatible games. The mechanics of the Nintendo interface are set up such that the game board is physically and electrically separated from the blood glucose meter board. Blood glucose results are displayed on the DIDGET meter only and not on the Nintendo gaming system.

Parental supervision and assistance is recommended for young children.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Contour Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
   k062058, k060470
3. Comparison with predicate:

Similarities		
Item	New Device DIDGET Blood Glucose Monitoring System	Predicate - k062058 Contour Blood Glucose Monitoring System
User interface	Same	settings for date, time, date/time format, high/low target ranges and test reminder alarms, and the ability to mark readings as pre-meal or post-meal
Blood Glucose Test Strip	Same	Contour test strip

Similarities		
Item	New Device DIDGET Blood Glucose Monitoring System	Predicate - k062058 Contour Blood Glucose Monitoring System
User interface	Same	settings for date, time, date/time format, high/low target ranges and test reminder alarms, and the ability to mark readings as pre-meal or post-meal
Coding for test strips	Same	Auto-coding
Test volume	Same	0.6 µl
Test time	Same	5 seconds
Control solution marking	Same	automatically recognize control solutions and exclude them from blood glucose averages
Strip technology	same	amperometric blood glucose detection methodology using Glucose Dehydrogenase (FAD)

Differences		
Item	New Device DIDGET Blood Glucose Monitoring System	Predicate - k062058 Contour Blood Glucose Monitoring System
Indications for use	DIDGET is intended for self-testing by persons with diabetes to monitor glucose in fresh capillary whole blood samples drawn from the fingertip only. It is intended for those ages four and older, with adult supervision as needed. The DIDGET 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 Blood Glucose Monitoring System is used for the measurement of glucose in whole blood. The Contour Blood Glucose Monitoring System is an over-the-counter (OTC) device used by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities. The Contour Blood Glucose Monitoring System is indicated for use with capillary, venous, and arterial whole blood samples and neonatal blood samples. Capillary samples may be drawn from the fingertip, palm, forearm, and in the case of neonates, the heel.
Measurement range	20 to 600 mg/dL.	10 to 600 mg/dL

Differences		
Item	New Device DIDGET Blood Glucose Monitoring System	Predicate - k062058 Contour Blood Glucose Monitoring System
Alternative site testing	Fingertip	fingertip, palm and forearm
Specimen types	Whole blood	capillary, venous or arterial whole blood
Neonatal use	No	indicated for neonatal use
Reference method	factory set with reference to plasma, whole blood or deproteinized whole blood	factory set with reference to plasma or whole blood

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

- ISO 15197, In vitro diagnostic test systems - requirements for in vitro whole blood glucose monitoring systems intended for use by patients for self testing in management of diabetes mellitus, 2003
- IEC 61010-1: Safety requirements for electrical equipment for measurement, control and laboratory use, 2001
- IEC 61010-2-101: Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-6: Particular requirements for in vitro diagnostic medical equipment, 2002
- UL 61010-1: Safety requirements for electrical equipment for measurement, control and laboratory use, 2004
- IEC 61326-1: Electrical equipment for measurement, control and laboratory use - EMC requirements, 2006

L. Test Principle:

Once a whole blood sample is applied to the sample chamber of the test strip, glucose measurement commences. Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip's electrodes. The current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Venous blood (hematocrit value of 45%+/-1%) was tested at five glucose concentration ranges: 30 – 50, 51 – 110, 111 – 150, 151 – 250 and 251 – 400mg/dL. Ten DIDGET meters with 10 replicates per meter (n=100) were used. The glucose concentration of each sample was checked by reference method immediately before the first and after the last measurement of meters. The within-run precision for all meters and concentrations tested were as follows:

Glucose Conc. (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
39.3	0.90	2.29
81.5	2.14	2.63
131.2	1.99	1.52
197.6	3.39	1.72
331.4	7.08	2.14

The Day to Day precision testing was performed using three levels of glucose control solutions using ten meters over a period of 10 days. The results are tabulated below.

Level	Low	Mid	High
Mean (mg/dL)	41.7	131.4	388.7
Standard Deviation	0.56	1.47	4.5
Coefficient of Variation (%)	1.36	1.12	1.16

b. Linearity/assay reportable range:
The assay measuring range of the device is 20 – 600 mg/dL. The sponsor conducted linearity studies to demonstrate that glucose measurements using their device are linear. Venous whole blood was collected and glucose adjusted to 7 concentration levels (0, 20, 50, 100, 200, 400, and 550 mg/dL). Eight DIDGET meters were tested at each glucose concentration with 3 replicates. The linear regression line for three lots was: $y = 0.994(x) + 0.0492$, $r^2 = 0.999$.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
Shelf life studies show that control solutions have a twenty-four month life-span and a six month shelf-life once control solution bottle is opened. The recommended storage temperature is 59° F - 86° F. Traceability for controls is referenced to the NIST SRM 917a (dry D-glucose).

d. Detection limit:
The detection limit is 20 mg/dL as supported by the linearity study described above.

e. Analytical specificity:
The interference studies including hematocrit effect for blood glucose measurement were established in the sponsor's predicate device (Contour Glucose Monitor – k062058) that uses the same glucose test system.

f. Assay cut-off:
Not applicable.

2. Comparison studies:
   a. Method comparison with predicate device:
   A method comparison study was performed with 123 subjects between the ages of 4

and 24 years. Capillary finger-stick testing was done where participants aged 8 and above tested themselves and the parent/guardian assisted with, or performed, testing for participants ages 4 to 7. The distribution of gender, diabetes type, and age for all 123 subjects were as follows.

Gender	Number	% of Total
Male	54	58
Female	69	42

Diabetes	Number	% of Total
Type 1	118	95.9
Type 2	5	4.1

Age Group	Number	% of Total
4 - 12	41	33.33
13 - 17	30	24.39
18 - 24	52	42.28

Of the 123 subjects used, 2 samples were excluded from testing as there were no YSI results. The range of concentrations of 121 samples was 53 – 463 mg/dL by the reference method. The linear regression line for the accuracy study was, $y = 0.99x – 0.72$, $r^2 = 0.969$. The accuracy for DIDGET meter vs. YSI in the format of ISO 15197 is given below.

Fingerstick accuracy for glucose concentrations < 75 mg/dL:
(DIDGET meter vs. YSI)

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6/9 (66.67%)	8/9 (88.89%)	9/9 (100%)

Fingerstick accuracy for glucose concentrations ≥ 75 mg/dL:
(DIDGET meter vs. YSI)

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
59/112 (52.68%)	90/112 (80.36%)	101/112 (90.18%)	109/112 (97.32%)

The glucose distribution of natural capillary samples did not cover the entire assay measuring range of the device. In order to achieve glucose concentrations across the entire measuring range of the meter, 47 venous blood samples were spiked or glycolyzed to obtain high or low glucose concentrations for testing. The range of concentrations for all 168 samples (capillary and modified) was 25 – 563 mg/dL by the reference method. The linear regression line for the accuracy study was, $y = 1.02x – 3.43$, $r^2 = 0.981$. The accuracy for DIDGET meter vs. YSI in the format of ISO 15197 is given below.

Fingerstick accuracy for glucose concentrations < 75 mg/dL:
(DIDGET meter vs. YSI)

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
19/28 (67.86%)	26/28 (92.86%)	28/28 (100%)

Fingerstick accuracy for glucose concentrations ≥ 75 mg/dL:
(DIDGET meter vs. YSI)

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
76/140 (54.29%)	117/140 (83.57%)	128/140 (91.43%)	137/140 (97.86%)

b. Matrix comparison:
Not applicable. Only capillary whole blood samples can be used with this device.

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):

4. Clinical cut-off:
   Not applicable.

5. Expected values/Reference range:
   Expected values for people without diabetes[1]:
   Fasting: 70-130 mg/dL
   2 hours after meals < 180 mg/dL
   [1]*American Diabetes Association: Standards of Medical Care in Diabetes(Position Statement). Diabetes Care 32 (Suppl.):S22, 2009.*

N. Instrument Name:
DIDGET Blood Glucose Monitoring System

O. System Descriptions:
1. Modes of Operation:
   Each test strip is single use and must be replaced with a new strip for each additional reading.
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:
   This device is intended to be used with capillary whole blood from the finger tip only. Since the whole blood sample is applied directly to the test strip, there are no special handling or storage issues.
5. Calibration:
   No calibration is required from the user. The meter accommodates auto-coding, in that each strip is designed and manufactured to code the meter appropriately when the strip is inserted.
6. Quality Control:
   Three levels of control are supplied with the device. Users are instructed to test control solutions when the meter is first used in order to verify that they can use the meter correctly. In addition they are instructed to run a control when a new vial of test strips is opened, when they suspect the meter or strips are not working correctly, if test results appear to be abnormally high or low, or are not consistent with the patient's symptoms. The user is referred to the troubleshooting section of the owner's manual if control results fall outside the assigned ranges.

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

The sponsor performed a readability assessment of the labeling and the lay user instructions are at 7.5 grade level or below.

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.