

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

A. 510(k) Number:

k092602

B. Purpose for Submission:

New Device – New glucose test strips with GDH-FAD methodology for marketed meters

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative coulometric assay, glucose dehydrogenase (GDH-FAD)

E. Applicant:

Abbott Diabetes Care, Inc.

F. Proprietary and Established Names:

FreeStyle Lite and FreeStyle Freedom Lite Blood Glucose Monitoring Systems

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1345; Glucose test system

2. Classification:

Class II

3. Product code:

NBW, System, Test, Blood Glucose, Over The Counter
LFR, Glucose Dehydrogenase, Glucose

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indications(s) for use:

FreeStyle Lite Blood Glucose Monitoring System

The FreeStyle Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm, and venous whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or

screening for diabetes mellitus, and is not intended for use on neonates or arterial blood.

FreeStyle Freedom Lite Blood Glucose Monitoring System

The FreeStyle Freedom Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm, and venous whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates or arterial blood.

- 3. Special conditions for use statement(s):
 - Not intended for use on neonates
 - Not for the diagnosis of or screening for diabetes mellitus
 - Not to be used for patients who are dehydrated, hypotensive or in shock
 - Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
 - Not for use on critically ill patients
 - Alternative site testing can only be done during times of steady state

- 4. Special instrument requirements:
FreeStyle Lite and FreeStyle Freedom Lite Blood Glucose meters

I. Device Description:

The FreeStyle Lite and FreeStyle Freedom Lite Blood Glucose Monitoring Systems contain a blood glucose meter (Lite and Freedom Lite, respectively), FreeStyle Lite test strips, FreeStyle control solution, lancing device and lancets. The only difference between the two meters is that the FreeStyle Lite meter has a backlight, with an additional button to operate it, while the FreeStyle Freedom Lite meter does not.

J. Substantial Equivalence Information:

- 1. Predicate device name(s):
FreeStyle Lite Blood Glucose Monitoring System

- 2. Predicate 510(k) number(s):
k070850

- 3. Comparison with predicate:

Similarities		
Item	Subject Device	Predicate
Indications for use	The FreeStyle Lite and FreeStyle Freedom Lite Blood Glucose Monitoring Systems are	Same

Similarities		
Item	Subject Device	Predicate
	specifically indicated for use on The FreeStyle Lite and FreeStyle Freedom Lite Blood Glucose Monitoring Systems are intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, forearm and palm, and venous whole blood. They are intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. They are not intended for the diagnosis of or screening for diabetes mellitus, and are not intended for use on neonates or arterial blood.	
Test Principle	Coulometric biosensor technology	Same
Sample Type	Venous or capillary whole blood	Same
Sample volume	0.3 µL	Same
Measurement range	20-500 mg/dL	Same
AST	Upper arm and palm	Same
Calibration	None required	Same
Second sample application	Within 60 seconds	Same
Measurement time	5 seconds	Same

Differences		
Item	Subject Device	Predicate
Enzyme	GDH-FAD	GDH-PQQ
Shelf life	12 months	18 months

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

- ISO 15197:2003- *In vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- ISO 14971:2007, Medical devices – Application of risk management to medical devices.
- EN 13640:2002, Stability testing of in vitro diagnostic medical devices.
- CLSI EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods.
- CLSI EP6-A: Evaluation of Linearity of Quantitative Measurement Procedures, A Statistical Approach.
- CLSI EP7-A2: Interference Testing in Clinical Chemistry.
- CLSI EP9-A2: Method Comparison and Bias Estimation Using Patient Samples.

- FDA Guideline, Review criteria for assessment of portable blood glucose monitoring in vitro diagnostic devices using glucose oxidase, dehydrogenase or hexokinase methodology.

L. Test Principle:

The FreeStyle Lite and FreeStyle Freedom Lite glucose meters, in conjunction with the Freestyle Lite test strips, utilize coulometric biosensor technology to quantitatively measure the glucose concentration in whole blood samples and in control solutions. The glucose biosensors recognize the glucose present in whole blood or control solutions by virtue of the specificity of the enzyme FAD dependent glucose dehydrogenase (GDH) present on the test strip. The electrons liberated by this reaction are transferred via a co-factor and mediator to the meter where they are read as a small electrical current. The magnitude of the charge measured over reaction time is directly proportional to the level of glucose in the applied sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor performed precision studies in accordance with the ISO 15197 guideline. Adjusted venous whole blood samples at 5 glucose levels (hematocrit range 35 to 50%) were used for within-day precision studies. Each concentration was tested 10 times each on 10 meters, using 3 test strip lots, for a total of 300 tests per blood glucose level. The reference value was determined by the YSI 2300 glucose analyzer. Results are summarized below:

	Level 1 30-50 mg/dL			Level 2 51-110 mg/dL			Level 3 111-150 mg/dL		
Lot	Average	SD	%CV	Average	SD	%CV	Average	SD	%CV
1	46.8	1.3	2.7	96.9	2.2	2.2	132.2	2.1	1.6
2	44.8	1.2	2.7	92.9	2.1	2.2	131.3	2.1	1.6
3	42.9	1.4	3.4	89.8	1.8	2.1	128.7	2.8	2.2

	Level 4 151-250 mg/dL			Level 5 251-400 mg/dL		
Lot	Average	SD	%CV	Average	SD	%CV
1	208.8	4.6	2.2	285.5	5.6	2.0
2	207.6	3.6	1.7	287.2	5.4	1.9
3	202.6	3.4	1.7	283.8	6.8	2.4

The sponsor also evaluated the day-to-day precision of the device using replicate measurements of glucose control solutions (low, normal, and high). Three different concentrations, using the same lot of control solutions, were tested on 10 meters, each tested in duplicate over 20 days with 3 strip lots. Results are summarized below:

	Level 1 40-70 mg/dL			Level 2 83-125 mg/dL			Level 3 248-372 mg/dL		
Lot	Average	SD	%CV	Average	SD	%CV	Average	SD	%CV
1	53.7	1.4	2.5	101.0	2.0	2.0	298.6	7.2	2.4
2	53.5	2.7	5.2	100.8	1.9	1.9	300.8	5.5	1.8
3	54.4	1.2	2.2	101.3	2.1	2.1	297.7	7.2	2.4

b. Linearity/assay reportable range:

The sponsor performed linearity studies using adjusted whole blood samples with 9 different glucose concentration ranges from 20 to 500 mg/dL. Duplicate measurements were made with each concentration on 6 meters and the results compared to those obtained using YSI 2300. Linear regression analysis resulted in: $y = 0.97x + 10.7$; $r^2 = 0.996$.

The claimed reportable range of the device is 20 to 500 mg/dL.

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

The method comparison was performed using the proposed device and YSI 2300 glucose analyzer.

Test strip stability was assessed in real-time and accelerated studies. The testing supported the claimed shelf life of 12 months when stored at 4-30°C with relative humidity of 5-90%.

The FreeStyle Control Solutions, Levels 1, 2, and 3 were previously cleared in k070850.

c. Detection limit:

The measuring range of the device is 20-500 mg/dL. This range was validated via the linearity study (see section M.1.b.).

d. Analytical specificity:

The sponsor performed interference studies with spiked venous blood samples at two glucose concentrations (100 and 300 mg/dL) that were prepared and divided into a test (dosed) pool and a control pool. The interferents were added to the sample and each sample was analyzed in duplicate using 3 test strip lots on six meters. The bias between control and dosed samples were calculated for each substance as well as the bias of the dosed sample from the control for each substance tested. With the exception of xylose, all biases (control to dosed sample and dosed sample to YSI) were within $\pm 10\%$. For xylose, a dose response study was conducted on 5 xylose levels (0-25 mg/dL) at two glucose concentrations (100 and 300 mg/dL). It was determined that the highest level of xylose at which no significant interference occurs is 6 mg/dL. A warning statement is included in the test strip insert that this device should not be used during xylose absorption testing. The table below lists all substances tested at concentrations with insignificant (<10%) interference:

Substance	Concentration with <10% interference (mg/dL)
Acetaminophen	20
Ascorbate	5
B-hydroxybutyrate	100
Bilirubin	20
Cholesterol	500
Creatinine	30
Dopamine	13
Ephedrine	10
Galactose	100
Ibuprofen	50
Lactate	100
Lactose	100
L-dopa	5
Maltose	100
Methyl-dopa	2.5
Pyruvate	10
Salicylic acid	50
Tetracycline	4
Tolazamide	100
Tolbutamide	100
Triglyceride	3000
Uric acid	40
Xylose	6

e. *Assay cut-off:*
Not Applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor conducted a combined accuracy and consumer study. Testing was conducted at 3 sites, with trained operators and a total of 179 lay-users. Each lay user participant performed their own fingerstick and tested their blood on the FreeStyle Lite meter using only the instructions in the user's manual and test strip insert. A trained operator then performed a second fingerstick and tested the blood on the same meter. Blood was also collected and measured on an YSI analyzer. The total range of samples tested was 33-492 mg/dL, with a hematocrit range of 27-58%. A total of 36 samples <50 mg/dL and >395 mg/dL were glycolyzed or spiked, respectively and tested by trained operators only. Linear regression results are presented below:

Trained operator $y = 0.94x + 0.3, r^2 = 1.00, x = 215$
 Lay user $y = 0.96x - 1.6, r^2 = 0.99, x = 179$

The study results met the ISO 15197 accuracy criteria where ninety-five percent (95%) of the individual glucose results fell within $\pm 15\text{mg/dL}$ of the YSI results at glucose concentrations $<75\text{mg/dL}$ and within $\pm 20\%$ at glucose concentrations $\geq 75\text{mg/dL}$.

For glucose concentrations $<75 \text{ mg/dL}$

	within $\pm 5 \text{ mg/dL}$	within $\pm 10 \text{ mg/dL}$	within $\pm 15 \text{ mg/dL}$
Trained operator	23/29 (79.3%)	29/29 (100%)	29/29 (100%)
Lay user	8/11 (72.7%)	11/11 (100%)	11/11 (100%)

For glucose concentrations $\geq 75 \text{ mg/dL}$

	within $\pm 5 \%$	within $\pm 10 \%$	within $\pm 15 \%$	within $\pm 20 \%$
Trained operator	126/186 (67.7%)	172/186 (92.5%)	185/186 (99.5%)	186/186 (100%)
Lay user	115/168 (68.5%)	160/168 (95.2%)	166/168 (98.8%)	167/168 (99.4%)

The sponsor conducted alternative site studies on the palm and upper arm at 2 clinical sites with a total of 151 lay users. Each participant obtained samples from either their palm or upper arm and tested these samples on the FreeStyle Lite meter using only the instructions in the user's manual and test strip insert. A trained operator then obtained palm and upper arm samples from each participant and tested these samples on the same meter. Venous blood was also collected and measured on a YSI analyzer. Linear regression results are presented below:

palm trained operator $y = 1.03 + 4.6, r^2 = 0.994, x = 74$
 lay user $y = 1.03 + 4.5, r^2 = 0.990, x = 74$

upper arm trained operator $y = 0.96 + 8.1, r^2 = 0.981, x = 77$
 lay user $y = 1.00 + 6.4, r^2 = 0.974, x = 77$

Both the palm and upper arm alternative site results met the ISO 15197 accuracy criteria where ninety-five percent (95%) of the individual glucose results fell within $\pm 15\text{mg/dL}$ of the YSI results at glucose concentrations $<75\text{mg/dL}$ and within $\pm 20\%$ at glucose concentrations $\geq 75\text{mg/dL}$.

For glucose concentrations $<75 \text{ mg/dL}$

		within ± 5	within ± 10	within ± 15

		mg/dL	mg/dL	mg/dL
Palm	Trained operator	1/5 (20%)	4/5 (80%)	5/5 (100%)
	Lay user	1/5 (20%)	3/5 (60%)	5/5 (100%)
Upper arm	Trained operator	0/1 (0%)	1/1 (100%)	1/1 (100%)
	Lay user	0/1 (0%)	1/1 (100%)	1/1 (100%)

For glucose concentrations ≥ 75 mg/dL

		within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
Palm	Trained operator	30/69 (43%)	54/69 (78%)	67/69 (97%)	69/69 (100%)
	Lay user	32/69 (46%)	54/69 (78%)	65/69 (94%)	67/69 (97%)
Upper arm	Trained operator	39/76 (51%)	68/76 (88%)	73/76 (95%)	75/76 (97%)
	Lay user	39/76 (51%)	60/76 (79%)	69/76 (91%)	72/76 (95%)

b. Matrix comparison:

Venous blood samples from 107 subjects was collected in EDTA tubes and from 109 subjects was collected in heparin tubes and assayed 6 times each on the FreeStyle Lite meter and YSI using 3 strip lots. The glucose concentrations of the samples were 65-444 mg/dL and the hematocrit range was 25-51 %. Linear regression results are presented below:

EDTA $y = 0.92 + 9.8, r^2 = 0.99, x = 642$

Heparin $y = 0.93 + 9.1, r^2 = 0.99, x = 654$

The study results met the ISO 15197 accuracy criteria where ninety-five percent (95%) of the individual glucose results fell within ± 15 mg/dL of the YSI results at glucose concentrations < 75 mg/dL and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL.

For glucose concentrations < 75 mg/dL

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
EDTA	5/12 (41.7%)	11/12 (91.7%)	12/12 (100%)
Heparin	8/11 (72.7%)	11/11 (100%)	11/11 (100%)

For glucose concentrations ≥ 75 mg/dL

	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
EDTA	500/630 (79.4)	618/630 (98.1%)	629/630 (99.8%)	629/630 (99.8%)

Heparin	523/642 (81.5%)	623/642 (97.0%)	635/642(98.9%)	639/642 (99.5%)
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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:

Expected blood glucose levels for a non-diabetic, non-pregnant adult (referenced from the American Diabetes Association, Clinical Practice Recommendations; Diagnosis and classification of diabetes mellitus. Diabetes Care, 2005; 28 (Suppl. 1); S37-S42.

Time	Range (mg/dL)
Fasting	less than 100
Two hours after meals	less than 140

N. Instrument Name:

FreeStyle Lite Blood Glucose Meter

FreeStyle Freedom Lite Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings.

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

Yes _____ or No X .

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

Yes _____ or No X .

2. Software:

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

Yes X or No _____

The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

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 and venous whole blood, which can be applied directly to the test strip.

5. Calibration:

No calibration is required by the user.

6. Quality Control:

The sponsor provides a normal control solution with the device. Two other levels (low and high) are available for purchase from the sponsor). An acceptable range for each control level is printed on the test strip vial label. The user is referred to the troubleshooting section of the owner's manual if control results fall outside these ranges.

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

Hematocrit Study:

A study to evaluate the effect of hematocrit was conducted on samples with 5 glucose concentrations (36-44, 81-99, 162-198, 253-297, 324-396, and 400-500 mg/dL) at 7 hematocrit levels (15, 20, 25, 40, 55, 60, and 65%). Each glucose level/hematocrit combination was tested in duplicate on 6 meters using 3 lots of test strips. Results of samples at each hematocrit level were compared to samples with the same glucose concentration at normal (40%) hematocrit as well as to the corresponding YSI value. All results met the acceptance criteria of $\pm 15\%$ which supports the claimed hematocrit range of 15-65%.

Altitude study:

An altitude study was performed at elevations up to 10,000 feet with 60 tests each of 3 different concentrations of glucose spiked whole blood spanning 36 to 440 mg/dL. Sea level results were compared to results at higher elevations and to YSI values, with all results meeting the sponsor's acceptance criteria of $\pm 10\%$

Temperature and humidity studies:

Temperature and humidity studies were conducted that demonstrated that the devices can be used at temperatures of 4 to 40°C and at a relative humidity of 5 to 90%, and stored at temperatures of 4 to 30°C with a relative humidity of 5 to 90%.

The sponsor provided a readability study and obtained Flesch-Kincaid grade level scores of 8 or lower for the User's Manual and test strip insert.

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.