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

A. 510(k) Number:

k051839

B. Purpose for Submission:

Premarket Notification 510(k) of the intention to market the FreeStyle Freedom Blood Glucose Monitoring System

C. Measurand:

Glucose

D. Type of Test:

Quantitative - Coulometric electrochemical sensor, PQQ Glucose Dehydrogenase

E. Applicant:

Abbott Diabetes Care

F. Proprietary and Established Names:

FreeStyle Freedom Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1345, Glucose test system

2. Classification:

   Class II

3. Product code:

   NBW, LFR

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use (below).

2. Indication(s) for use:

The FreeStyle Freedom™ Blood Glucose Monitoring System is specifically indicated for use on the finger, forearm, upper arm, thigh, calf and hand.

The FreeStyle Freedom™ Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in 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 it is not intended for use on neonates or arterial blood.

3. Special conditions for use statement(s):

This product is intended for over-the-counter use.

Patients should not test on alternate sites (palm, back of the hand, forearm, upper arm, thigh, or calf) when they think their blood glucose is rapidly falling, such as within two hours of exercise or a rapid-acting insulin injection or insulin pump bolus. Testing with a fingertip sample may identify a hypoglycemic level (low blood sugar) sooner than a test with a forearm or palm sample.

Patients should not test on alternate sites when it has been less than two hours after a meal, a rapid-acting insulin injection or insulin pump bolus, physical exercise, or they think their glucose level is changing rapidly.

Patients should not test on alternate sites when they are concerned about the possibility of hypoglycemia.

4. Special instrument requirements:

The FreeStyle Freedom™ Blood Glucose Meter

I. Device Description:

The FreeStyle Freedom™ Blood Glucose Monitoring System is an electrochemical biosensor consisting of a glucose-oxidizing enzyme on a disposable test strip (the electrochemical sensor) and a hand-held current measuring device. Software internal to the hand-held device converts the measured current into glucose concentration using an algorithm that depends on the ambient temperature and the activity of the enzyme on the test strip. The user has the ability to validate the operation of the system by using glucose control solutions provided with the system.

The FreeStyle Freedom™ Blood Glucose Monitoring System consists of a hand-held blood glucose meter, test strips, and two levels of control materials. Each lot of test strips has a code number implying lot-specific calibration. The strip characteristics associated with each code number are pre-programmed and permanently stored in the hand-held meter.

The meter is turned on by strip insertion. The user must select a code number corresponding to their vial of strips via the meter's interface.   After selecting the correct code, the user applies blood or a drop of control solution to the strip. The meter completes the glucose assay in 5 or more seconds. The meter's software converts the charge read off the test strip into a plasma glucose concentration and displays the value on the meter's LCD screen. The user has the ability to validate the operation of the system by using glucose control solutions provided with the system.

J. Substantial Equivalence Information:

1. Predicate device name(s):

    FreeStyle 600 Blood Glucose Monitoring System

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

    k050500

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Enzyme	Same	PQQ dependent glucose dehydrogenase
Detection Method	Same	Coulometric electrochemical sensor
Analyte	Same	D-glucose
Minimum Sample Size	Same	0.3 uL
Test Strip	Same	Cleared in predicate submission
Humidity Range	Same	5% - 90%

Similarities		
Item	Device	Predicate
Hematocrit	Same	15% - 65%
Operating Temperature Range	Same	5 °C – 40 °C

Differences		
Item	Device	Predicate
Blood sample	Capillary whole blood, Fresh venous blood (within 30 minutes of draw) for professional use only	Venous, capillary, arterial, and neonatal whole blood
Concentration Range	20-500 mg/dL	20-600 mg/dL
Measurement time	5 seconds average	15 seconds

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

CLSI EP05-A2: Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline-Second Edition

CLSI EP06-A: Evaluation of the Linearity of Quantitative Analytical Methods; Approved Guideline

CLSI EP07-A2: Interference Testing in Clinical Chemistry; Approved Guideline- Second Edition

CLSI EP09-A2: Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Second Edition

ISO 15197: In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

FDA Guidance "Guidance for Industry: In Vitro Diagnostic Glucose Test System"
   Available at: http://www.fda.gov/cdrh/ode/glucose.pdf

FDA Guidance "General Principles of Software Validation; Final Guidance for Industry and FDA Staff"
   Available at: http://www.fda.gov/cdrh/comp/guidance/938.pdf

FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
   Available at: http://www.fda.gov/cdrh/ode/guidance/337.pdf

L. Test Principle:

The FreeStyle Freedom™ meter utilizes coulometric biosensor technology to quantify glucose concentrations. Specifically, it correlates the total charge produced by the glucose oxidation reaction to a glucose concentration. Since complete oxidation of glucose in a sample can take in excess of 100 seconds, the total charge derived from the reaction is estimated from a partial reaction profile.

A mediator molecule shuttles electrons between a glucose-oxidizing enzyme and the working electrode on the strip. This rapid electron transport by the mediator maintains the enzyme in an oxidized state capable of reacting with glucose. Unlike the predicate, the re-oxidation of the mediator is accelerated and allows the glucose oxidation to proceed faster.

Software internal to the hand-held device uses the charge collected during the measurement time and the measured ambient temperature to project an estimated time course for the reaction. The software converts the estimate of the total amount of glucose to a concentration which is then displayed to the user.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. *Precision/Reproducibility:*

      The company demonstrated the repeatability of their meter by performing within run precision studies on venous blood. One venous blood sample was adjusted to five different concentrations of glucose spanning the range claimed by the meter (20 mg/dL – 500 mg/dL). The company conducted the within-run precision study following guidelines in ISO 15197 and CLSI EP5-A2. The YSI was used as the reference standard for comparison. The company multiplied the YSI measurements by 1.12 to determine the plasma equivalent glucose values.

      For the within-meter, within-vial precision studies, the company made 10 replicate measurements at each glucose concentration for each meter-vial pair. The company used vials from 3 different manufacturing lots in this study. A summary of the results is presented in the table below:

Strip Lot#	YSI*1.12	Mean	SD, within vial	CV, within vial
	35.8	36.3	2.6	7.0
	90.9	84.4	3.0	3.6
1	136.6	129.1	2.9	2.2
	206.9	186.1	5.8	3.1
	339.4	300.3	8.5	2.8
	33.5	35.4	2.0	5.5
	93.7	89.8	2.4	2.6
2	141.1	138.5	3.5	2.5
	201.9	192.4	5.8	3.0
	345.2	314.9	11.0	3.5
	43.5	45.0	2.0	4.3
	95.1	92.9	3.0	3.2
3	143.9	139.1	3.0	2.1
	206.1	192.7	5.2	2.7
	342.4	313.4	8.3	2.6

The average standard deviation observed in the within-meter, within-vial study was 2.5 mg/dL for glucose concentrations below 100 mg/dL with a corresponding CV of 4.4%. For glucose concentrations above 100 mg/dL, the within-meter, within-vial average standard deviation was 6.0 mg/dL with a corresponding CV of 2.7%.

The company demonstrated their within-lot precision of their device by measuring 5 different glucose concentrations 10 times across 16 meters. A summary of the results is presented in the table below:

Strip Lot#	YSI*1.12	Mean	SD, within lot	CV, within lot
	35.8	36.3	3.1	8.7
	90.9	84.4	4.4	5.2
1	136.6	129.1	5.4	4.2
	206.9	186.1	8.9	4.8
	339.4	300.3	14.3	4.8
	33.5	35.4	2.6	7.4
	93.7	89.8	3.2	3.5
2	141.1	138.5	5.3	3.8
	201.9	192.4	7.8	4.0
	345.2	314.9	15.2	4.8
	43.5	45.0	2.8	6.3
	95.1	92.9	3.7	4.0
3	143.9	139.1	4.1	2.9
	206.1	192.7	6.1	3.2
	342.4	313.4	10.2	3.3

The average standard deviation for measurements made within the same lot of strips at concentrations below 100 mg/dL was 3.3 mg/dL with a corresponding CV of 5.9%. For measurements above 100 mg/dL, the average standard deviation for measurements made within the same strip lot was 8.6 mg/dL with a corresponding CV of 4.0%.

The company assessed their day-to-day precision using measurements on 3 different concentrations of control solutions. The study involved 2 measurements per meter per day for 20 days using 3 lots of strips. A summary of these measurements:

Control Solution	Average meter Reading (mg/dL)	Strip Lot 0526364	Strip Lot 0526401	Strip Lot 0526332	Average Std. dev.	Average %CV
Low	55.1	1.6	1.7	2.1	1.8	3.3
Normal	104.1	3.1	3.2	3.2	3.2	3.0
High	328.6	10.8	11.6	12.8	11.7	3.6

b. *Linearity/assay reportable range:*

The company followed CLSI EP6-A in demonstrating the linear response of their device. They adjusted the unpooled blood of three different donors to 9 different YSI glucose concentrations. The average YSI glucose values obtained were as follows: 28, 78, 140, 192, 265, 320, 376, 438, 489 mg/dL. Each concentration of each blood sample was measured 3 times on 2 different lots of strips across 6 meters for a total of 972 measurements. Readings from the YSI were scaled by 1.12 for comparison. The proposed device demonstrated a linear relationship to the YSI with a slope of 0.8266, intercept of 9.6057 and a r-squared value of 0.9909.
In the clinical studies using fresh capillary blood, a linear regression of fingerstick measurements using the Freedom device vs. a YSI capillary fingerstick measurement yielded a line with a slope of 0.971, an intercept of 8.620 mg/dL, and an r-value of 0.981. The samples ranged from 50 mg/dL to 500 mg/dL by the YSI method.

In the clinical studies using fresh venous blood, a linear regression of 198 venous blood measurements using the Freedom device vs. a YSI venous measurement yielded a line with a slope of 0.922, an intercept of 19.063 and an r-value of 0.994. The samples ranged from 65 mg/dL to 490 mg/dL by the YSI method.

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

Data on expected values, traceability, and stability for the glucose control solutions used with this device was supplied in a previous submission, k050500.

d. *Detection limit:*

See linearity study above. Another study was performed by repeated testing using out-of-range blood samples with 3 lots of strips. Pooled blood from 3 donors was adjusted to an out-of-range low glucose concentration of 13 mg/dL. The results are summarized below:

For the low glucose limit, the company tested 3 lots of strips:

Average glucose (mg/dL)	Strip Lot	Total tests	"LO' results	Numeric results
13	1	36	34	2
	2	36	35	1
	3	36	30	6
	Total	108	99	9
			91.7%	8.3%

e. *Analytical specificity:*

Hematocrit Sensitivity

The company assessed the sensitivity of their device to variations in Hematocrit by testing on blood from three donors. They used 6 different meters and 3 lots of strips to measure 5 glucose concentrations spanning the claimed concentration range of the meter. At each glucose concentration, they adjusted the sample Hematocrit to one of 5 levels spanning the claimed Hematocrit range for the device. Each glucose and hematocrit combination was measured twice.
The table below summarizes the company's findings for the average bias over the 3 lots and 6 meters:

Average Glucose (mg/dL)	Hematocrit				
	15%	25%	40%	50%	65%
23.7	-2.3 mg/dL	-2.8 mg/dL	-2.0 mg/dL	-0.8 mg/dL	0.3 mg/dL
132.9	13.6%	5.8%	0.7%	1.0%	2.3%
249.6	16.6%	11.8%	-0.1%	-1.3%	-1.6%
362.4	15.3%	12.1%	1.3%	-4.6%	-4.7%
470.7	2.8%	3.0%	-0.7%	-7.2%	-9.2%

Temperature Sensitivity

The company assessed the sensitivity of their device to variations in temperature by

testing on blood from three donors. They used 6 different meters and 3 lots of strips to measure 5 glucose concentrations spanning the claimed concentration range of the meter. At each glucose concentration, they determined the observed glucose for three temperatures: 1) the claimed lower limit of the meter, 5 °C, 2) the claimed upper limit of the meter, 40 °C, and 3) 25 °C.

The table below summarizes the company's findings for the average bias over the 3 lots and 6 meters:

Average Glucose (mg/dL)	5°C	25°C	40°C
23.2	-3.8 mg/dL	-3.3 mg/dL	-3.0 mg/dL
137.0	5.1%	0.7%	6.2%
259.6	4.2%	2.7%	9.3%
367.3	3.2%	-0.7%	7.8%
481.7	-1.1%	0.2%	4.5%

Impact of Humidity

The company assessed the sensitivity of their device to variations in humidity by testing on blood from three donors. They used 6 different meters and 3 lots of strips to measure 5 glucose concentrations spanning the claimed concentration range of the meter. At each glucose concentration, they determined the observed glucose at a relative humidity of 5%, 50%, and 90%. Measurements were made in duplicate. All humidity studies were conducted at 25 °C.

The table below summarizes the company's findings for the average bias over the 3 lots and 6 meters:

[Glucose] , mg/dL	Observed Bias relative to 25°C/50% Relative Humidity		
	5%	50%	90%
23.2	-2.3 mg/dL	-2.1 mg/dL	-1.8 mg/dL
137.0	1.3%	2.9%	2.5%
259.6	1.6%	4.7%	2.3%
367.3	2.8%	4.2%	1.4%
481.7	1.1%	3.3%	-0.7%

Effect of Blood pH

The company assessed the sensitivity of their device to variations in blood pH by varying the carbon dioxide content of a sample of venous blood. They used 6 different meters and 3 lots of strips to measure 5 glucose concentrations spanning the claimed concentration range of the meter. At each glucose concentration, they determined the observed glucose at a pH of 7.15, 7.4, and 7.61. Measurements were
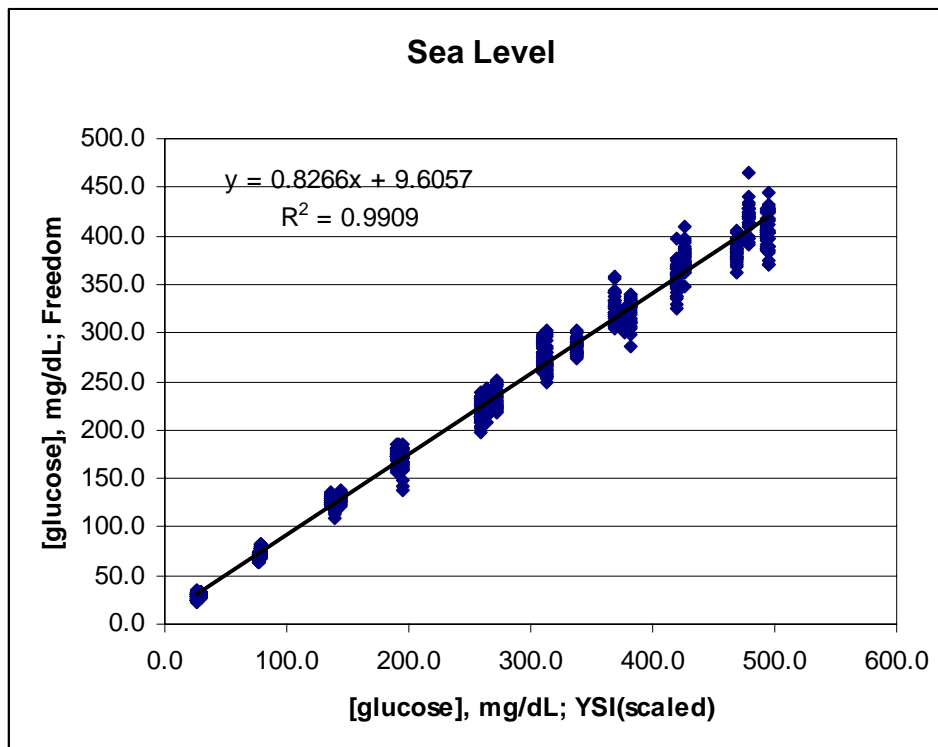
made in duplicate.

The table below summarizes the company's findings for the average bias over the 3 lots and 6 meters:

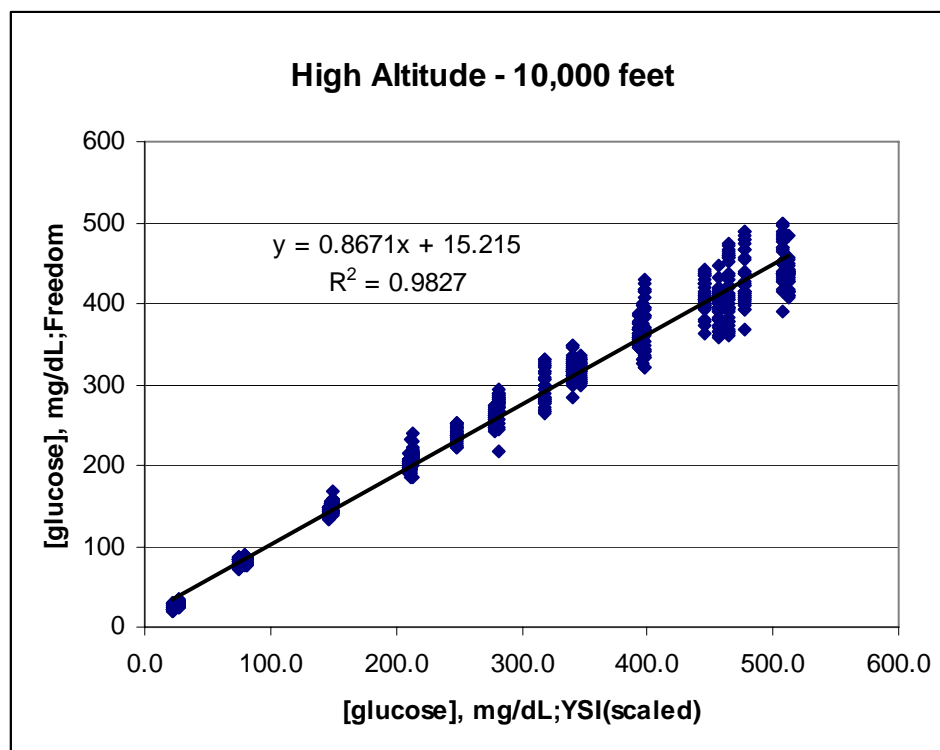| [Glucose], mg/dL	Average		
	pH = 7.4	pH = 7.15	pH = 7.61
26.8	-1.8 mg/dL	3.1 mg/dL	0.5 mg/dL
134.1	-2.4%	-0.5%	-0.8%
253.7	1.4%	1.7%	2.6%
381.4	2.6%	1.2%	4.2%
499.2	-1.7%	-3.1%	0.3%

Altitude Effect

The company assessed the variability in their device as a function of altitude by performing a linearity study at sea level and at a site at approximately 10,000 feet in elevation. The company used 6 different meters and 3 lots of strips to measure 9 glucose concentrations spanning the claimed concentration range of the meter. Measurements were made in duplicate.

The following graph illustrates the performance of the submitted device at sea level:

The following graph illustrates the performance of the submitted device at an altitude of 10,000 feet:

High Altitude - 10,000 feet

$$y = 0.8671x + 15.215$$
$$R^2 = 0.9827$$

Y-axis: [glucose], mg/dL;Freedom
X-axis: [glucose], mg/dL;YSI(scaled)

The following graph illustrates the average bias from sea level over the 3 lots and 6 meters:

Glucose value mg/dL	Bias from Sea Level		
	Lot 1	Lot 2	Lot 3
25.5	-4.1 mg/dL	-4.6 mg/dL	-2.8 mg/dL
78.5	6.7 mg/dL	7.3 mg/dL	6.7 mg/dL
148.4	10.6 %	10.7 %	10.5 %
211.6	10.1 %	10.6 %	12.8 %
269.9	8.4 %	9.9 %	12.6 %
334.6	4.3 %	12.9 %	8.8 %
395.8	4.8 %	12.2 %	6.4 %
455.6	2.3 %	11.5 %	1.8 %
499.5	2.8 %	6.6 %	2.2 %

Impact of Chemical Interference

The company assessed the impact of endogenous and exogenous chemicals on the performance of their device. The company used 6 different meters and 3 lots of strips to measure 1 approximately normal glucose concentration from a venous blood sample. Chemicals tested for interference were added by spiking. Measurements were made in duplicate.

The following graph illustrates the performance of the submitted device at sea level:

Interfering Agent	Concentration tested, mg/dL	Observed Difference in Reading (%)
Acetaminophen	20	1.1%
Ascorbic acid	3	2.9%
Bilirubin	20	-0.7%
Cholesterol	500	4.3%
Creatinine	30	0.2%
Dopamine	13	1.4%
Ephedrine	10	0.1%
Ibuprofen	40	3.5%
Lactic acid	60	1.9%
L-dopa	5	1.1%
m-dopa	2.5	2.0%
Salicylic acid	50	-2.0%
Tetracycline	4	-1.1%
Tolazamide	100	0.2%
Tolbutamide	100	3.2%
Triglyceride	3000	-1.7%
Uric acid	20	3.5%
Carbohydrates		
Galactose	100	**94.9%**
Lactose	100	**67.5%**
Maltose	100	**61.7%**
Xylose	100	**101.9%**

The company found that high levels of sugars other than glucose, which are often found in dialysis solutions, interfere with their device. The company added a warning to their user manual explicitly cautioning users about this problem.

Double Dipping

In the concentration range of 90-100 mg/dL, measurements of a single application of blood had a median distance of 5.0 mg/dL from the scaled YSI measurement. In the concentration range of 90-100 mg/dL, measurements made using two sequential applications of blood (a double dip) had a median distance of 4.0 mg/dL from the scaled YSI measurement.
In the concentration range of 360-370 mg/dL, measurements of a single application of blood had a median distance of 40.7 mg/dL from the scaled YSI measurement. In the concentration range of 360-370 mg/dL, measurements made using two sequential applications of blood (a double dip) had a median distance of 36.7 mg/dL from the scaled YSI measurement.

f. *Assay cut-off:*

Not applicable for a device of this type.

2. Comparison studies:

a. *Method comparison with predicate device:*

The company performed a clinical study to assess the ability of lay users to use the device to measure their glucose. A total of 186 subjects divided across 3 sites participated in the study. For each subject, the lay user performed a single finger stick measurement. For comparison, a trained operator also performed a single finger stick measurement. The trained operator also obtained additional fingerstick blood for measurement by a YSI 2300 STAT Plus Blood Glucose analyzer. Measurements on the YSI were performed twice. Six subjects were dropped from the subsequent data evaluation. Four were dropped due to missing YSI reference measurements. Two were excluded due to varying YSI reference measurements.
A linear least squares regression of the lay users' measurements versus the YSI 2300 STAT reference had a slope of 0.92, an intercept of 14.3 mg/dL, and an r-value of 0.99. A linear least squares regression of the trained operator measurements versus the YSI 2300 STAT reference had a slope of 0.95, an intercept of 12.9 mg/dL, and an r-value of 0.97. A linear least squares regression of the lay user measurements using the Freedom meter versus the trained operator measurements using the Freedom meter had a slope of 0.97, an intercept of 2.7 mg/dL, and a r-value of 0.98.

Number and % of results within YSI reference (all values were ≥ 75 mg/dL)

User	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Lay user	98/180 54.4%	154/180 85.6%	173/180 96.1%	177/180 98.3%
Trained operator	93/180 51.7%	148/180 82.2%	163/180 90.6%	172/180 95.6%

b. *Matrix comparison:*

Not applicable for a device of this type.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable for a device of this type.

b. *Clinical specificity:*

Not applicable for a device of this type.

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

The company conducted a clinical study to demonstrate the accuracy of meter when used on the finger and forearm. 229 subjects in two sites participated in the study. A total of 7 patients were dropped from the study due to deviations in protocol. Measurements made by a medical technologist were compared to capillary and venous YSI plasma results. Two different lots of strips were used at one site. Three different lots of strips were used at the other. The level of testing varied at the two sites. After exclusions, a total of 955 fingerstick measurements and 190 measurements of the forearm were performed. In addition, a venous blood sample was obtained.

A linear regression of fingerstick measurements using the Freedom device vs. YSI capillary fingerstick measurement yielded a line with a slope of 0.971, an intercept of 8.620 mg/dL, and an r-value of 0.981. The samples ranged from 50 mg/dL to 500 mg/dL by YSI method.

A linear regression of forearm measurements using the Freedom device on subjects who had not eaten in more than 2 hours vs. YSI fingerstick measurement yielded a line with a slope of 0.98, an intercept of 1.893 mg/dL, and an r-value of 0.97.

A linear regression of forearm measurements using the Freedom including subjects who had recently eaten (72 of 190 forearm measurements) vs. YSI fingerstick measurement yielded a line with a slope of 0.931, an intercept of 8.634 mg/dL, and an r-value of 0.968.

A linear regression of 198 venous blood measurements using the Freedom device vs. YSI venous measurement yielded a line with a slope of 0.922, an intercept of 19.063 and an r-value of 0.994.

The company tested the performance of their device on the alternate sites claimed in their user manual. A YSI 2300 served as the reference method. After exclusions, 51 subjects participated in the trial. Subjects were tested by a technician first on a fingertip, then palm, forearm, upper arm, calf, thigh, and then an additional finger tip. For testing on the palm, participants were evenly divided for testing on the thenar region and hypothenar region.

The company used a Passing Bablok regression to calculate the slope and intercept of their alternate site data using scaled YSI measurements as a reference. The results of this analysis is as follows:

Alternate Site	Slope	Intercept	R-value	N
Upper Arm	0.999	1.897	0.821	51
Thenar	1.056	-2.208	0.891	24
Forearm	1.067	-2.735	0.806	51
Hypothenar	1.069	-2.427	0.946	27
Thigh	1.154	-16.380	0.756	51
Calf	1.185	-17.825	0.786	51

To evaluate the use of the back of the hand (base of the thumb and fore finger) as an alternate site, glucose values from 52 subjects were compared to scaled YSI measurements, ranging from 77 mg/dL to 246 mg/dL. 50/52 or 96% of the values were within 20% of the scaled YSI values.

4. Clinical cut-off:

Not applicable for a device of this type.

5. Expected values/Reference range:

The normal fasting glucose range for a non-diabetic adult is 70 to 110 mg/dL. (3.9 to 6.1 mmol/L)[1]. One to two hours after meals, normal glucose values should be less than 120 mg/dL (6.7 mm0l/L)[2].

[1]Burtis CA Ashwood ER, eds: Tietz Textbook of Clinical Chemistry. 2nd
[2]Krall LP and Beaser RS: Joslin Diabetes Manual. Lea and Febiger. Philadelphia 1989. p. 138.

N. Instrument Name:

FreeStyle Freedom Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

Test strips can only be used once. Users must replace the strip before taking an additional reading. The meter is designed to exclude the feature that allows a user to change the unit of measure.

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 for use with fresh capillary whole blood. Since the sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

    Each bottle of test strips has a code number which is used to calibrate the meter. The user confirms that the code number on the test strip bottle matches the code number in the instrument. If the bottle and meter codes do not match, the user must change the meter's code setting by depressing the "c" and "m" buttons on the meter until the correct number is displayed. No further calibration is required of the user.

6. Quality Control:

    The sponsor provides two levels of glucose control solutions with this device. To mark a test result as a control, the user depresses the "c" button on the meter for 2 seconds. Measurements marked as a control are excluded from supplemental data analysis supported by the meter (e.g., 14 day average glucose). An acceptable range of measurement for each control level is printed on the test strip vial label. If control results fall outside these ranges, the user is referred to a list of troubleshooting steps and the customer care line.

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

The meter supports memory for storing 250 measurements and supplemental data analysis, such as the 14 day average glucose concentration mentioned above. The user can program the meter with up to 4 timed alarms. By inserting an interface cable into the meter, users can download their measurement history to a personal computer.   Verification and validation information supplied by the company supports these performance claims.

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.