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

A. 510(k) Number:

k153330

B. Purpose for Submission:

New Device

C. Measurand:

Capillary, arterial, and venous whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose Dehydrogenase (GDH-NAD)

E. Applicant:

Abbott Diabetes Care Inc.

F. Proprietary and Established Names:

FreeStyle Precision Neo H 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 - Blood glucose test system, over the counter

   LFR - glucose dehydrogenase, glucose

4. Panel:

   (75) Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for use:

   The Freestyle Precision Neo H Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, and from venous and arterial whole blood.

   The Freestyle Precision Neo H Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices.

   The system should not be used for the diagnosis of or screening for diabetes or for neonatal testing.

   The Freestyle Precision Neo H Blood Glucose Test Strips are for use with the Freestyle Precision Neo H Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the finger, and from venous and arterial whole blood.

3. Special conditions for use statement(s):
   - The system should not be used for the diagnosis of or screening for diabetes.
   - The test strip has not been evaluated for alternative site testing.
   - The test strip is not designed for use with serum or plasma samples.
   - Only single-use, auto-disabling lancing devices should be used with this system.
   - Test results may be erroneously low if the patient is severely dehydrated, severely hypotensive, in shock or in a hyperglycemic-hyperosmolar state (with or without ketosis).
   - This system has not been evaluated in the critically ill.
   - This system should not be used to test neonates.

4. Special instrument requirements:

   Freestyle Precision Neo H Meter

I. Device Description:

The Freestyle Precision Neo H Blood Glucose Monitoring System includes the FreeStyle Precision Neo H Meter and the FreeStyle Precision Neo H Blood Glucose Test Strips. The FreeStyle Precision Neo H Blood Glucose Test Strip remains unchanged compared to the test strips of the predicate device cleared under k132511. Only the brand name of the glucose test strip has been changed from Freestyle Precision Pro Glucose Test Strip to FreeStyle Precision Neo H Blood Glucose Test Strips. The system is also used with the MediSense Glucose and Ketone Control Solutions (k983504, 3 levels, LO, MID, and HI) and the FreeStyle Auto-Assist Neo Data Management System.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   FreeStyle Precision Pro Blood Glucose and Beta-Ketone Monitoring System

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

   k132511

3. Comparison with predicate:

Similarities		
Item	Candidate Device Freestyle Precision Neo H Blood Glucose Monitoring System k153330	Predicate Device FreeStyle Precision Pro Blood Glucose and Beta-Ketone Monitoring System k132511
Indication for Use	Intended for the quantitative measurement of glucose (sugar) in whole blood as an aid to monitor the effectiveness of a diabetes control program.	Same
Glucose Sample types	Fresh capillary whole blood from the finger, and venous and arterial blood samples	Same
Hematocrit Range	15-65%	Same
Glucose Measuring Range	20-500 mg/dL	Same
Operating Temperature	59° to 104°F (15°-40° C)	Same

Similarities		
Item	Candidate Device Freestyle Precision Neo H Blood Glucose Monitoring System k153330	Predicate Device FreeStyle Precision Pro Blood Glucose and Beta-Ketone Monitoring System k132511
Operating Humidity	10-90%	Same
Glucose Sample volume	0.6 microliters	Same
Glucose Assay Time	5 seconds	Same

Differences		
Item	Candidate Device Freestyle Precision Neo H Blood Glucose Monitoring System K153330	Predicate Device FreeStyle Precision Pro Blood Glucose and Beta-Ketone Monitoring System k132511
Measurand	Whole blood glucose	Whole blood glucose and β- ketone (beta-hydroxybutyrate)
Data Upload	USB Data Cable	USB Data Cable, Docking Station or Wireless
Data Management System	FreeStyle Auto Assist Neo Data Management System	Precision Web Point-of-Care Health Management System
Altitude	10,000 feet above sea level	7,200 feet above sea level
Meter Display	e-ink screen	Pixel LCD screen
Button Display	Touch Press-button	Keypad

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

CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition (2003).

CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition (2005).

CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003).

L. Test Principle:

The FreeStyle Precision Neo H Meter measures glucose amperometrically. The glucose biosensor is capable of recognizing the glucose present in whole blood or control solutions by virtue of the glucose specificity of the enzyme GDH present on the glucose 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 size of the current is directly proportional to the level of the glucose in the applied sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within run precision was performed using venous whole blood samples spiked with glucose to 5 glucose levels. Three test strip lots and 10 meters were used for this study. The samples tested ranged from 30 to 400 mg/dL. Each sample was tested 10 times on each of 10 meters (n=100 total). The mean values and coefficients of variation were calculated for each sample and are summarized below:

Glucose Level (mg/dL)	Strip Lot	YSI Plasma (mg/dL)	n	Meter Reading (mg/dL)	SD (mg/dL)	%CV
30-50	1	48	100	45	1.9	4.3
	2		100	47	1.9	4.0
	3		100	47	2.1	4.6
	Combined				2.0	4.3
51-110	1	81	100	79	3.1	3.9
	2		100	81	2.8	3.5
	3		100	83	3.2	3.9
	Combined				3.1	3.8
111-150	1	143	100	137	4.5	3.3
	2		100	138	3.9	2.8
	3		100	141	4.4	3.1
	Combined				4.3	3.1
151-250	1	235	100	221	6.6	3.0
	2		100	218	5.9	2.7
	3		100	223	7.7	3.5
	Combined				6.8	3.1
251-400	1	371	100	346	10.0	2.9
	2		100	349	9.4	2.7
	3		100	345	11.2	3.2
	Combined				10.2	2.9

The intermediate precision evaluation was performed with three levels of glucose control solutions using 3 test strip lots and 10 FreeStyle Precision Neo H Meters. Each sample was tested in replicates of 20 for twenty days. The mean values and coefficients of variation were calculated for each sample and are summarized below.

Glucose Level	Strip Lot	Nominal Glucose (mg/dL)	N	Meter Reading (mg/dL)	SD (mg/dL)	CV %
1	1	46	400	43	2.1	5.0
	2	46	400	44	2.3	5.1
	3	47	400	43	2.5	5.7
		Combined			2.3	5.3
2	1	95	400	92	3.3	3.6
	2	96	400	92	3.4	3.7
	3	97	400	93	3.6	3.9
		Combined			3.4	3.7
3	1	300	400	287	8.5	3.0
	2	304	400	291	8.9	3.1
	3	302	400	284	9.5	3.3
		Combined			9.0	3.1

b. Linearity/assay reportable range:

Linearity was evaluated using venous whole blood samples at 9 different glucose levels (20-25, 45-55, 75-90, 120-140, 190-210, 260-280, 330-350, 400-420 and 480-500 mg/dL). Three blood samples were used at each level and the actual concentrations ranged from 20.0 to 496.2 mg/dL (20.0, 20.2, 22.9, 48.9, 52.5, 54.6, 78.0, 78.5, 83.1, 128.1, 129.8, 130.4, 198.5, 199.7, 260.9, 265.5, 266.7, 329.6, 330.2, 331.9, 406.5, 408.2, 411.1, 495.0, 495.6, 496.2 mg/dL) as measured by the reference method. Each sample was tested in replicates of 10 on each of 3 strip lots resulting in a total of 30 replicates for each strip lot and glucose level. The values from the FreeStyle Precision Neo H Meter were compared with those obtained from the reference method (YSI). The results from regression analysis are summarized below:

Lot 1: $y = 0.97x + 3.428$, $R^2=0.997$
Lot 2: $y = 0.96x + 2.675$, $R^2=0.995$
Lot 3: $y = 0.96x + 2.327$, $R^2=0.997$

The results of the study support the sponsor's claimed glucose measurement range of 20 to 500 mg/dL.

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

Traceability:
The FreeStyle Precision Neo H Blood Glucose Monitoring System is traceable to the NIST SRM 917c reference material.

Test Strip Stability:
FreeStyle Precision Neo H Blood Glucose Test Strip remains unchanged compared to the test strips of the predicate device cleared under k132511. The test strips are individually foil wrapped. Storage stability information was presented for the Freestyle Precision Pro Glucose Test Strip to support an 18 month shelf life when stored at 39-86 °F (4-30 °C).

Control Solution Stability:
The control solutions compatible for use with the current device (MediSense Glucose and Ketone Control Solutions) were previously cleared and stability and value assignment was established in k983504. The shelf life of the control solutions are 18 months at 39-86°F (4-30°C). Once opened, the controls are stable for 90 days at 39-86°F if tightly closed after use.

d. Detection limit:

The reportable range for the FreeStyle Precision Neo H Blood Glucose Monitoring System is 20 to 500 mg/dL. This range was verified by the linearity study (M.1.b).

e. Analytical specificity:

The interference study was designed according to CLSI EP7-A2 guideline. The sponsor assessed the potential interference from twenty nine common endogenous and exogenous interfering substances by spiking two venous whole blood glucose concentration intervals, (50-100 mg/dL and 250-350 mg/dL with interfering substances). Each sample was tested in replicates of 10 (three lots of strips). Bias from reference was compared between the samples with and without spiked substances to determine whether a particular substance significantly interferes with glucose measurement. The sponsor claims that there is no significant interference from the potential interfering substances at concentrations tested in the table below:

Compound	**The highest concentration at which no interference is observed (mg/dL)**
Acetaminophen	20
Amoxicillin	7.5
Ascorbate	2.5
Beta-hydroxybutyrate	100
Bilirubin (unconjugated)	20
Captopril	0.5
Cholesterol	500
Creatinine	30
Dopamine	0.1
Ephedrine	10

Compound	The highest concentration at which no interference is observed (mg/dL)
Galactose	100
Gentisic Acid	3.6
Glutathione, reduced	16
Hemoglobin	200
Ibuprofen	50
Icodextrin	460
L-dopa	5
Lactate	100
Lactose	100
Na+	500
Maltose	200
Methyl-dopa	2.5
Pyruvate	10
Parlidoxy Iodide (PAM)	205
Salicylic acid	50
Tetracycline	4
Tolazamide	100
Tolbutamide	100
Triglyceride	3000
Uric acid	40
Xylose	45

The sponsor has included the following in the labeling:

- Vitamin C (ascorbic acid >2.5 mg/dL) might affect the reliability of your blood glucose results. If you are taking vitamin C, your glucose results may not be accurate:
- Do not use during intravenous infusion of high-dose ascorbic acid.
- Do not use during xylose absorption testing, as xylose may produce falsely elevated glucose results during a xylose absorption test for diagnostic evaluation of malabsorption.

f. Assay cut-off:

Not applicable.

2. Comparison studies:
   a. *Method comparison with predicate device:*

To assess system accuracy, results from the FreeStyle Precision Neo H Blood Glucose Monitoring System were compared to a reference method, YSI 2300 Stat Plus Glucose Analyzer. Trained operators obtained the samples and results for all matrices (capillary, arterial and venous blood).

Capillary (fingerstick) samples:
Capillary samples from 174 participants with glucose concentrations ranging from 29-438 mg/dL, obtained using YSI 2300 Stat Plus Glucose Analyzer. Among those, 10 samples were altered to obtain glucose concentrations < 50 mg/dL or > 400 mg/dL for a total of 184 samples tested. Three test strip lots were tested per center and patients were tested from two centers. The results relative to reference are summarized in the tables below:

System Accuracy Results for Glucose concentration <75mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Trained Operator	7 / 10 (70.0%)	10 / 10 (100.0%)	10 / 10 (100.0%)

System Accuracy Results for Glucose concentration ≥75mg/dL

	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Trained Operator	118 / 174 (67.8%)	158 / 174 (90.8%)	172 / 174 (98.9%)	173 / 174 (99.4%)

Regression (Meter Results vs. YSI Reference)

	Slope	Intercept (mg/dL)	r	No. Reps
Trained Operator	0.97	1.7	0.990	184

Arterial Samples:
One hundred and eleven (111) leftover arterial blood specimens from lithium heparinized syringes in one clinical study center were used in the study within 30 minutes of completion of all medically-directed testing. Glucose concentrations ranging from 39.5-270 mg/dL were obtained using the reference method. Results from the candidate device were compared to those obtained from the reference method. The results are summarized below:

System Accuracy Results for Glucose concentration <75mg/dL

Within ±5mg/dL	Within ±10mg/dL	Within ± 15 mg/dL
15/20 (75.0%)	20/20 (100.0%)	20/20 (100.0%)

System Accuracy Results for Glucose concentration ≥75mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ± 20 %
52/91 (57.1%)	84/91 (92.3%)	90/91 (98.9%)	91/91 (100.0%)

Regression (Meter Results vs. YSI Reference)

Slope	Intercept (mg/dL)	r	No. Reps
0.97	-1.2	0.993	111

Venous samples:

One hundred and ten (110) subjects were recruited into the study at one clinical study center. Venous blood samples ranging from 59 to 342 mg/dL according to the reference method (YSI) were tested by a technician using three test strip lots. Results from the candidate device were compared to those obtained from the reference method. The results are summarized below:

Venous Whole Blood System Accuracy Results for Glucose concentration <75mg/dL

Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
4 / 4 (100.0%)	4 / 4 (100.0%)	4 / 4 (100.0%)

Venous Whole Blood System Accuracy Results for Glucose concentration ≥75mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
137/210 (65.2%)	194/210 (92.4%)	210/210 (100.0%)	210/210 (100.0%)

Venous Whole Blood Regression (Meter Results vs. YSI Reference)

Slope	Intercept (mg/dL)	r	No. Reps
0.95	5.0	0.990	214

b. Matrix comparison:

Anticoagulant study:
Venous blood samples were drawn into lithium heparin and EDTA vacutainer tubes. Results on the candidate device from each anticoagulant tube were compared to results obtained on the reference method (YSI). Results support the use of lithium heparin and EDTA as anticoagulants with use with the FreeStyle Precision Neo H Blood Glucose Monitoring System. The sponsor includes the following in the labeling: Do not use tubes containing fluoride or oxalate.

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):
User Performance Study:

Finger stick (capillary) data:
To assess the performance of the FreeStyle Precision Neo H Blood Glucose Monitoring System in the hands of lay-users the sponsor performed a study with 165 lay-user participants who collected their own fingerstick capillary sample. The samples ranged in glucose from 43-358 mg/dL as measured by YSI 2300 Stat Plus Glucose Analyzer. The results relative to reference (YSI) are summarized in the tables below:

System Accuracy Results for Glucose concentration <75mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lay User	1 / 4 (25.0%)	4 / 4 (100.0%)	4 / 4 (100.0%)

System Accuracy Results for Glucose concentration ≥75mg/dL

	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Lay User	102 / 161 (63.4%)	144 / 161 (89.4%)	156 / 161 (96.9%)	159 / 161 (98.8%)

Linear regression:

	Slope	Intercept (mg/dL)	r	No. Reps
Lay User	0.97	3.8	0.982	165

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:
   The expected glucose range for a non-diabetic, non-pregnant fasting adult is under 100 mg/dL. Two hours after meals, levels should be less than 140 mg/dL.[1]

   1. American Diabetes Association. Classification and Diagnosis of Diabetes; Diabetes Care January 2016; 39:S13-S22.

N. Instrument Name:

FreeStyle Precision Neo H 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 ___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:
   The FreeStyle Precision Neo H Blood Glucose Meter will store 1,000 patient results, including control solution results.

4. Specimen Sampling and Handling:
   The FreeStyle Precision Neo H Glucose Monitoring System is intended to be used with capillary whole blood from the finger, venous or arterial whole blood. Since the whole blood sample is applied directly to the test strip, there are no special handling or storage issues.

5. Calibration:
   The FreeStyle Precision Neo H Meter is manually calibrated. A calibrator strip is packaged with each carton of test strips. The user inserts the calibrator strip into the meter. The meter turns on automatically. The lot number appears in the display window. The user must check that the lot number on the meter display window matches with the number on the test strip calibrator and the last five digits on both the test strip foil packet and test strip instructions for use. The calibration procedure programs the meter with the lot number, expiration date and test strip technology. This procedure requires the calibrator supplied with this test strip package and a FreeStyle Precision Neo H Meter, available separately.

6. Quality Control:
   Three levels of aqueous glucose control solutions are available for use with this system. No controls solution is provided with FreeStyle Precision Neo H Blood Glucose Monitoring System. Instructions on how to order the control solutions are included in the user manual. The meter has a function for the user to select that they wish to run a control solution to prevent control results from being stored in the internal memory as patient results. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results when the measurements are performed in the "control solution mode". An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

   The FreeStyle Precision Neo H Meter also includes a quality control reminder feature for glucose control solution tests. The quality control Reminder notifies the user a quality control test is due. The quality control reminder can be set for hourly (1-23 hours) or daily (1-30 days) intervals and can be enabled and disabled by the healthcare professional (HCP).

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

1. Sample volume Study:
   The FreeStyle Precision Neo H Blood Glucose Monitoring System was tested with venous blood at three glucose concentration intervals (40-60, 100-120, and 380-420 mg/dL) and three specimen volumes. For each glucose interval, the specimen volumes were adjusted to 0.4, 0.6, and 1.0 µL. Each sample was measured in three replicates for each of the three strips and the same sample was also measured by an established laboratory reference method (YSI 2300 analyzer). The bias for above replicates in each test strip lot calculated. Results support the claimed minimum sample volume of 0.6 µL and the meter error code for insufficient sample volume.

2. Hematocrit Study: The effect of different hematocrit levels on the performance of the FreeStyle Precision Neo H Blood Glucose Monitoring System was evaluated using venous whole blood samples with hematocrit levels of 15, 20, 30, 42, 50, 60 and 65% and spiked with glucose to achieve concentrations between 42 and 448 mg/dL (42, 43, 44, 45, 66, 67, 68, 69, 104, 108, 109, 111, 112, 212, 213, 217, 218, 219, 337, 338, 339, 340, 446, 448, 450, 452 and 453 mg/dL). Each hematocrit/glucose concentration combination was then tested 10 times and the individual values were compared with those obtained from YSI reference analyzer. The device demonstrated adequate performance at glucose concentrations between 42 and 448 mg/dL when the hematocrit concentrations are between 15% and 65% to support the claimed hematocrit range of 15-65%.

3. Altitude study: Venous whole blood samples were collected from 3 blood donors and spiked with glucose into 3 concentration levels (45, 113 and 385 mg/dL) at two study sites (sea level and 10,000 feet). Blood glucose target concentrations were then verified by the reference YSI glucose analyzer at the same site. The results demonstrate acceptable bias to YSI to support the claims in the labeling that altitudes up to 10,000 feet have no significant effect on blood glucose measurements from the FreeStyle Precision Neo H Blood Glucose Monitoring System.

4. Temperature and humidity studies: The sponsor performed temperature and humidity studies using venous blood samples to evaluate temperatures ranging from 59ºF to 104ºF (15ºC to 40ºC) and relative humidity from 10% to 90%. Meter results were compared to YSI reference analyzer. Four temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity. No significant effect (relative to YSI reference analyzer) was observed with the temperature and humidity combinations tested. The results support the claims in the labeling that the system can be used in conditions of 59ºF to 104ºF with relative humidity of 10 to 90%.

5. Infection Control Studies: The FreeStyle Precision Neo H Blood Glucose Monitoring System is intended for multiple-patient use. Clorox Healthcare Bleach Germicidal Wipe with EPA registration # 67619-12, was validated demonstrating complete inactivation of live virus for use with the meter. The sponsor also performed robustness studies demonstrating that there was no change in performance or in the external materials of the meter after 10,950 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 3 years of multiple-patient meter use. Labeling

was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. The sponsor provided appropriate documentation certifying that acceptable electromagnetic testing (EMC) had been performed and the FreeStyle Precision Neo H Blood Glucose Monitoring System was found to be compliant.

7. Customer service is available 24 hours a day, 7 days a week by calling 1-800-527-3339 or 1-877-878-0880.

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.