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

A. 510(k) Number:

k140371

B. Purpose for Submission:

New Device

C. Measurand:

Capillary 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 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:

   FreeStyle Precision Neo Blood Glucose Monitoring System is for use outside the body only (in vitro diagnostic use) in the quantitative measurement of glucose in fresh whole blood for self-testing by lay users from the fingers. It is not intended to be used for testing neonatal blood samples or the diagnosis or screening of diabetes.

   The FreeStyle Precision Neo System is indicated for home (lay user) in the management of patients with diabetes. It is intended to be used by a single person and should not be shared.

   The FreeStyle Precision Neo Blood Glucose Test Strips are for use with the FreeStyle Precision Neo Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

3. Special conditions for use statement(s):

   It is intended to be used by a single person and should not be shared.

   For over-the-counter use.

   It is not intended to be used for testing neonatal blood samples or the diagnosis or screening of diabetes.

   Not for use on patients who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.

   This device should not be used on critically ill patients.

4. Special instrument requirements:

   Freestyle Precision Neo Blood Glucose Meter

I. Device Description:

The Freestyle Precision Neo Blood Glucose Monitoring System includes the FreeStyle Precision Neo Blood Glucose Meter and the FreeStyle Precision Neo Blood Glucose Test Strips. The apply blood symbol is displayed for the user to apply blood to the test strip until the meter begins the test. The meter detects trigger current from the test strip when enough blood has covered the strip electrodes and the test countdown will start. When the countdown is complete a test result is displayed on the meter screen. The unit of measure displayed on the meter screen is fixed in mg/dL and cannot be modified by the user.

The following items are included in the Freestyle Precision Neo Blood Glucose Monitoring System:

- 1 FreeStyle Precision Neo Meter
- 2 Owner's Setup Guides
- 1 Carry Case
- 1 Freestyle Lancing Device II
- 10 Lancets

The following items are compatible with the FreeStyle Precision Neo System and are available separately:

- FreeStyle Precision Neo Blood Glucose Test Strips
- MediSense Glucose and Ketone Control Solutions (cleared in k983504)
- USB Cable
- FreeStyle Lancing Device II
- Thin Lancets

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ReliOn Ultima Blood Glucose Monitoring System

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

   k083223

3. Comparison with predicate:

Similarities/Differences		
Item	Predicate Device ReliOn Ultima Blood Glucose Monitoring System (k083223)	Candidate Device Freestyle Precision Neo Blood Glucose Monitoring System
Intended Use/Indications for Use	For in vitro diagnostic use in the quantitative measurement of glucose in fresh whole blood for self-testing by lay users or by health care professionals. It is not intended to be used for testing neonatal blood samples.	Same
	Single or Multiple Patient Use	Single patient use only
Detection method	Amperometry	Same
Enzyme	GDH-NAD	GDH-NAD
Calibration Coding	Non-Coding	Same
Sample type	Capillary, venous, arterial whole blood	Capillary whole blood
Sample sites	finger, forearm, upper arm or base of thumb	Finger tip
Sample volume	0.6 µL	Same
Sample test time	5 seconds	Same
Test range	20 - 500 mg/dL	Same
Operating Temperature	50° - 122°F	Same

Operating Humidity	10% - 90%,	Same
Hematocrit range	30 - 60%	15-65%
Altitude Study	Up to 7200 feet	Up to 10,000 feet
Memory	450 events	1000 events

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

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

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

EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003).

ISO 14971 - Medical devices — Application of risk management to medical devices (2007).

L. Test Principle:

The FreeStyle Precision Neo Meter (in conjunction with blood glucose test strips) utilizes amperometric technology to quantitatively measure the glucose concentration in capillary whole blood samples from the fingertip and in MediSense Glucose and Ketone Control Solutions.

The FreeStyle Precision Neo Meter measures glucose electrically. 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. <u>Analytical performance:</u>

   a. Precision/Reproducibility:
   Within-Run Precision:

Venous blood from one donor was adjusted with glucose to five glucose levels (i.e. 30-50, 51-110, 111-150, 151-250, 251-400) across the claimed range and tested on three lots of strips and on 10 meters. Each sample was tested in 10 replicates per meter and per trip lot, giving a total of 100 measurements/lot (n=100). Results are summarized below:

Glucose Level, mg/dL	Strip Lot	n	Meter Reading, mg/dL	SD, mg/dL	CV, %
30-50	1	100	40	1.6	4.0
	2	100	42	1.8	4.3
	3	100	41	1.7	4.1
	Combined			1.7	4.1
51-110	1	100	91	3.5	3.8
	2	100	88	2.8	3.2
	3	100	90	3.7	4.1
	Combined			3.3	3.7
111-150	1	100	137	5.0	3.7
	2	100	129	3.6	2.7
	3	100	134	6.2	4.6
	Combined			5.1	3.8
151-250	1	100	235	7.3	3.1
	2	100	228	6.4	2.8
	3	100	236	8.8	3.7
	Combined			7.5	3.2
251-400	1	100	372	10.3	2.8
	2	100	357	11.3	3.2
	3	100	377	13.6	3.6
	Combined			11.8	3.2

Intermediate precision was evaluated on 3 levels (50, 120, and 350mg/dL) of Glucose control solutions using three lots of test strips and ten meters. For each test strip lot, each control solution was measured in duplicate per day using 10 meters over 20 days (N=400/lot). Results are summarized below:

Glucose Level	Strip Lot	n	Meter Reading, mg/dL	SD, mg/dL	CV, %
1	1	400	45	2.1	4.6
	2	400	43	2.2	5.0
	3	400	42	1.8	4.2
	Combined			2.0	4.6
2	1	400	94	3.7	4.0
	2	400	92	3.5	3.8
	3	400	90	3.3	3.7
	Combined			3.5	3.8
3	1	400	302	9.0	3.0
	2	400	289	10.1	3.5
	3	400	286	10.1	3.5
	Combined			9.8	3.3

b. Linearity/assay reportable range:

Linearity was evaluated using 3 sets of venous blood samples each with 9 glucose levels ranging in glucose concentrations of24, 50, 81, 128, 193, 264, 335, 413, 486 mg/dL. Each sample was tested in replicates of 10 on each of 3 strip lots. The mean values from the FreeStyle Precision Neo Meter for each strip lot (Y) were compared with the reference value obtained from the YSI method (X). The results from regression analysis are summarized below:

Lot 1: $y = 0.98x+6.966$, $R^2=0.997$
Lot 2: $y = 0.96x+6.425$, $R^2=0.995$
Lot 3: $y = 1.00x +6.682$, $R^2=0.995$

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

Traceable to NIST SRM 91, dry D-glucose.

Stability

Test strip closed vial stability:

Real time stability was performed to support a shelf-life of 18 months at the recommended storage condition, at a temperature ranging from 36°F-86°F (4°C to 30°C) and between 10%-90% relative humidity. The study protocol and acceptance criteria were found acceptable. 4

Open vial stability:
NA. The strips are individually wrapped.

Control Solution:
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^{o}F. Once opened, the controls are stable for 90 days at 39-86^{o}F if tightly closed after use.

d. Detection limit:

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

e. Analytical specificity:

29 endogenous and exogenous substances were screened for interference by spiking high concentrations of each substance into 2 venous whole blood samples, one at low glucose value of 50-100 mg/dL, and one at high glucose value of 250-350 mg/dL. Each sample was tested in replicates of 10 on each of 3 strip lots. The % difference between the spiked sample and the control sample with no substance was calculated. The sponsor defines no significant interference as bias within ±10%.

Among the 29 substances tested, sodium and xylose exhibited interference at low glucose concentration of 50-100 mg/dL. Dose repose studies were performed and the upper limit for no interference was at 50 mg/dL for xylose, and 477mg/dL for sodium.

Based on the test results, the sponsor state in the strip insert:

1) The system exhibits interference from Xylose at low glucose concentration levels. Do not use during xylose absorption testing.
2) The system exhibits no interference from the following substances above the concentrations shown below:

Substance	Upper Limit of Physiological / Therapeutic Concentration, mg/dL	Highest Concentration Tested with no Observed Interference, mg/dL
Acetaminophen	3	20
Amoxicillin	2.5	7.5
Ascorbate	1.5	2.5
ß-hydroxybutyrate	<7.6	265
Bilirubin	1.2	20
Captopril	0.1	0.5
Cholesterol	<200	503
Creatinine	1.3	5
Dopamine	0.03	0.1
EDTA	180	720
Ephedrine	0.01	10
Galactose	20	15
Gentisic Acid	0.6	1.8
Heparin	1500*	5600*
Ibuprofen	5	50
Lactate	20	59
Lactose	-	100
L-dopa	0.2	5.0
Maltose	100-120	110
Methyl-dopa	0.75	1.5
Pyruvate	0.9	10
Salicylic acid	30	60
Sodium	414	477
Tetracycline	0.5	1.5
Tolazamide	2.8	15
Tolbutamide	10	64
Triglyceride	<150	1500
Uric acid	7.2	24

To mitigate potential confusion that users will misinterpret labeling claims of no interference from therapeutic heparin and EDTA with the ability to use these as anticoagulants, the FreeStyle Precision Neo Blood Glucose Test Strip labeling state the following in the "Limitations of the Procedure" section: "This test strip is not designed for use with arterial, venous, neonatal, serum or plasma samples and should not be used on blood samples collected in tubes containing EDTA or heparin."

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

To assess system accuracy, a total of 215 capillary blood samples with glucose YSI values ranging from 29- 438 mg/dL were evaluated by the health care professionals**.** Three meters and 3 lots of strips were randomly assigned during the study. To obtain low or high end glucose values, 10 capillary blood samples were glycolyzed or spiked. Therefore, 225 samples were available for the test.

The meter results relative to YSI are summarized in the tables below:

Glucose < 75 mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
10	7/10 (70%)	9/10 (90.0%)	10/10 (100%)

Glucose ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
215	125/215 (58.1%)	187/215 (87.0%)	207/215 (96.3%)	213/215 (99.1)

Liner Regression:
Y=1.01X-0.3; r=0.988, N=225

b. Matrix comparaison:

Not applicable. Capillary whole blood from the finger is the only indicated 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):

User Performance Study:

A user performance study was performed to compare the lay user self-test results and the YSI method. The study was performed at 2 clinical sites in the US and 165 subjects were evaluated. The study participants were provided with the User's Manual in English, and performed fingerstick tests on their own. A technician also collected capillary blood from each participant for measurement on YSI after the participant obtained and ran their sample. The range of glucose values for the finger stick samples was 53-358 mg/dL measured by YSI. 2 test strip lots were randomly assigned in the study.

Fingerstick Glucose < 75 mg/dL

Number of test results	Within ± 5 mg	Within ± 10 mg	Within ± 15 mg
4	3/4 (75%)	4/4 (100%)	4/4 (100%)

Fingerstick Glucose ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
161	98 / 161 (60.9%)	140 / 161 (87.0%)	159 / 161 (98.8%)	160 / 161 (99.4%)

Liner Regression:

Y=1.00X-0.4; r=0.984 (N=165)

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   The sponsor states the expected glucose range for a non-diabetic, non-pregnant fasting adult to be under 100 mg/dL, and two hours after meals, the levels should be less than 140 mg/dL

   Reference citation: "American Diabetes Association. Standards of Medical Care in Diabetes—2013. Diabetes Care 2013; 6(Suppl.1) S11-S66."

N. Instrument Name:

FreeStyle Precision Neo 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 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 _____

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. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   The meter is automatically coded. No calibration is required by the user.

6. Quality Control:
   Three levels of aqueous glucose control solutions are available (sold separately) for use with this system. No controls solution is provided with the FreeStyle Precision Neo 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.

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

1. **Hematocrit Study:**
   The effect of different hematocrit levels was evaluated using venous whole blood samples with hematocrit levels of 15 – 65% (15, 20, 30, 42, 50, 60, 65%) spiked with glucose to achieve target concentrations of 40-50, 100-120, 210-230, 330-350 and 440-460 mg/dL. Results of samples at each hematocrit level were compared to samples with the same glucose concentration at normal (42%) hematocrit as well as to the corresponding YSI value. The data supports the claimed hematocrit range of 15 – 65%.

2. **Altitude study**:
   Venous whole blood samples collected from 3 blood donors were spiked with glucose into 3 concentration levels (40-50, 100-120, and 380-420 mg/dL). The glucose meter readings at an altitude of 10,000 feet were compared to the readings at sea level as well as the YSI method. 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 Blood Glucose Monitoring System.

3. **Sample volume study**:

   The sponsor performed a study to verify the test strip sample volume requirement and the test strip fill error requirement established for the proposed FreeStyle Precision Neo Meter. Blood samples at glucose levels of 40-50, 100-120 and 380-420 mg/dL were tested on the meter and compared to the YSI values at 3 sample volumes of 0.4, 0.6 and 1 µL. The results support the claimed sample volume of 1 µL and the error message, "E-3", is triggered and displayed on the meter when an insufficient sample is applied.

4. **Temperature and humidity studies**:
   The sponsor performed temperature and humidity studies using venous blood samples to evaluate temperatures ranging from 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 15 to 40°C with relative humidity of 10 to 90%.

5. **Readability Assessment:**
   The readability of the labeling using a Flesch-Kincaid analysis were found to be written at the 5.6 grade level for the user manual and 7.7 grade level for the strip insert. During the lay user study described above in Section M.3.c, the participants were asked to complete a questionnaire to evaluate the ease of use of the device and the clarity of the English language labeling. Overall the users scored 5.5 out of 6 for ease of use (1, strongly disagree; 6, strongly agree).

6. **EMC Testing:**
   The sponsor provided documentation certifying that acceptable electromagnetic testing (EMC) had been performed.

7. **Infection Control Studies:**
   The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Healthcare Bleach Germicidal Wipes (EPA Registration #67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 522 cleaning and 522 disinfection steps with the Clorox Healthcare Bleach Germicidal wipes. The robustness studies were designed to simulate 2 cleaning and disinfection cycles each week for 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

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

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10, and 21 CFR 801.109(b)(1) to contain the following language "Precautions: For In Vitro Diagnostic Use Only."

R. Conclusion:

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