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

A. 510(k) Number:

k171941

B. Purpose for Submission:

Expansion of the indications for use of FreeStyle Precision Neo Blood Glucose Test Strips (k140371) to include compatibility with the FreeStyle Libre Reader's built-in meter (P160030).

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 Test Strips

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

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 Blood Glucose Test Strips are for use outside the body only (in vitro diagnostic use) with the FreeStyle Libre Reader's built-in meter as components of the FreeStyle Libre Flash Glucose Monitoring System to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. They are not intended to be used for testing neonatal blood samples or for the diagnosis or screening of diabetes.

   The FreeStyle Precision Neo Blood Glucose Test Strips are indicated for home (lay) user in the management of patients with diabetes. They are intended to be used by a single person and should not be shared.

3. Special conditions for use statement(s):

   - For over-the-counter use.
   - Test strips are intended to be used by a single person and should not be shared.
   - Test strips are not intended to be used for testing neonatal blood samples or for the diagnosis or screening of diabetes.
   - This test strip is not designed for use with arterial, venous, neonatal, serum or plasma samples and is not for use with blood samples collected in tubes containing EDTA or heparin.
   - Samples with hematocrit levels that are above the stated range may give incorrect glucose results.
   - Test results may be erroneously low if the patient is severely dehydrated, or severely hypotensive, in shock or in a hyperglycemic-hyperosmolar state (with or without ketosis).
   - This device should not be used to test critically ill patients.

4. Special instrument requirements:

   FreeStyle Libre Reader's built-in meter

I. Device Description:

The FreeStyle Precision Neo Blood Glucose Test Strips are compatible with the FreeStyle Precision Neo Blood Glucose Meter (cleared under k140371 as part of the FreeStyle Precision Neo Blood Glucose Monitoring System) or the FreeStyle Libre Reader's built-in meter (P160030), and are used for the quantitative measurement of glucose in capillary whole blood samples. There have been no changes to the fundamental technology of the FreeStyle Precision Neo Blood Glucose Test Strips since clearance with the FreeStyle Precision Neo Blood Glucose Meter in k140371. Additionally, the glucose measurement

engine and signal processing are the same for the FreeStyle Libre Reader's built-in meter and the FreeStyle Precision Neo Blood Glucose Meter.

The FreeStyle Libre Reader's built-in-meter is a component of a handheld device (Reader), which is part of the FreeStyle Libre Flash Glucose Monitoring System. The Reader has a built-in strip port with blood glucose meter functionality, a user interface, and can communicate with an on-body assembly (Sensor) that collects glucose data.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   FreeStyle Precision Neo Blood Glucose Monitoring System

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

   k140371

3. Comparison with predicate:

Similarities		
Item	Candidate device	Predicate device (k140371)
Intended use	Intended to be used to quantitatively measure glucose in fresh capillary whole blood samples for the management of patients with diabetes.	Same
Detection method	Amperometry	Same
Enzyme	GDH-NAD	Same
Sample type	Fresh capillary whole blood from the finger	Same
Sample volume	0.6 µL	Same
Glucose assay time	5 seconds	Same
Glucose test range	20-500 mg/dL	Same
Hematocrit range	15% - 65%	Same
Altitude	10,000 feet	Same
Calibration coding	No coding required	Same
Differences		
Item	Candidate device	Predicate device (k140371)
Compatible Meters	The FreeStyle Precision Neo Blood Glucose Test Strips are for use outside the body only (in vitro diagnostic use) with the FreeStyle Precision Neo Blood Glucose Meter or the FreeStyle Libre Reader's built-in meter as	The FreeStyle Precision Neo Blood Glucose Test Strips are for use outside the body only (in vitro diagnostic use) with the FreeStyle Precision Neo Blood Glucose Meter.

Similarities		
Item	Candidate device	Predicate device (k140371)
	components of the FreeStyle Libre Flash Glucose Monitoring System.	

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

- ISO 14971:2007/(R)2010, Medical Devices – Applications of Risk Management to Medical Devices
- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition
- CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
- CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition

L. Test Principle:

The FreeStyle Precision Neo Blood Glucose Test Strips (in conjunction with a compatible blood glucose meter) 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 Blood Glucose Test Strips measures glucose electrically when used in conjunction with a compatible blood glucose meter. 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. The blood glucose concentration (mg/dL) is displayed on the reader.

M. Performance Characteristics (if/when applicable):

The performance of the FreeStyle Precision Neo Blood Glucose Test Strips with the FreeStyle Precision Neo Blood Glucose Meter was established in k140371. The performance of the FreeStyle Precision Neo Blood Glucose Test Strips with the FreeStyle Libre Reader's built-in-meter component of the FreeStyle Libre Flash Glucose Monitoring System (P160030) is described below.

1. Analytical performance:

   a. *Precision/Reproducibility:*

      Within-run precision was performed using human venous blood samples (collected into sodium heparin tubes) adjusted to five blood glucose levels (30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, and 251-400 mg/dL). Each glucose

level was tested on 10 FreeStyle Libre Reader's built-in-meters with 3 lots of FreeStyle Precision Neo Blood Glucose Test Strips. Each sample was tested over 1 day in 10 replicates per meter and per test strip lot, giving a total of 100 measurements per lot for a total of 300 measurements for each glucose level. Blood samples were also tested by a comparator measurement procedure (YSI 2300 Stat Plus). Results are summarized below:

Within-run precision

Glucose Level (mg/dL)	n	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	300	41	2.5	6.2
51-110	300	90	4.0	4.5
111-150	300	128	5.2	4.0
151-250	300	205	8.3	4.0
251-400	300	329	12.0	3.7

Intermediate precision was evaluated using 3 levels of glucose control solution. Each control level was analyzed in duplicate on 10 meters using 3 lots of test strips each day for a total of 10 days, giving a total of 200 measurements per lot for a total of 600 measurements for each glucose level. Results are summarized below.

Intermediate: Within-lot precision

Glucose Level (mg/dL)	n	Mean (mg/dL)	SD (mg/dL)	CV (%)
Low	600	43	2.2	5.2
Medium	600	90	3.0	3.3
High	600	284	9.7	3.4

b. Linearity/assay reportable range:

Linearity testing was performed according to CLSI EP06-A. Three (3) sets of human venous blood samples (collected into heparin tubes) were adjusted to 9 blood glucose levels: 21 mg/dL, 48 mg/dL, 84 mg/dL, 122 mg/dL, 198 mg/dL, 269 mg/dL, 346 mg/dL, 403 mg/dL, 497 mg/dL. Each sample was measured with 10 FreeStyle Libre Reader's built-in-meters with 3 lots of FreeStyle Precision Neo Blood Glucose Test Strips and the values compared to a comparator method (YSI 2300 Stat Plus). Results from the regression analysis:

Test Strip Lot	Slope	Y-intercept	R^2
1	0.988	0.899	0.997
2	0.992	-0.638	0.997
3	0.986	-0.381	0.997
Combined	0.988	-0.041	0.997

The reportable range for glucose measurements is 20-500 mg/dL. If a sample glucose level is below 20 mg/dL, 'LO' will be displayed on the glucose meter. If a sample glucose level is above 500 mg/dL, 'HI' will be displayed on the glucose meter.

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

Traceability

The FreeStyle Precision Neo Blood Glucose Test Strips are traceable to NIST SRM 917c, D-Glucose (Dextrose). The method comparison study was performed using the FreeStyle Precision Neo Blood Glucose Test Strips with FreeStyle Libre Reader's built-in-meters and YSI 2300 Stat Plus as the comparator method (see Section 2.a.).

Test Strip Stability

Stability of the FreeStyle Precision Neo Blood Glucose Test Strips was previously established in k140371. The test strips have a shelf-life of 18 months at the recommended storage temperature of 36°F-86°F and relative humidity of 10%-90%. The test strips are individually wrapped in foil packets; therefore, open vial stability claims are not provided.

d. Detection limit:

See linearity/assay reportable range in section M.1.b. above.

e. Analytical specificity:

Interference studies were conducted according to CLSI EP07-A2. Endogenous or exogenous substances, each at one concentration, were added to venous whole blood samples (collected into heparin tubes) adjusted to 2 glucose levels (50-100 mg/dL and 250-350 mg/dL). Each test sample containing interferent or control sample without interferent was measured with 10 FreeStyle Libre Reader's built-in-meters and 3 lots of FreeStyle Precision Neo Blood Glucose Test Strips as well as by YSI 2300 Stat Plus. Bias from YSI 2300 Stat Plus was compared between the samples with and without interferent. Results are shown below.

Substance	Highest concentration with no significant interference (mg/dL except where noted)
Acetaminophen	20
Amoxicillin	7.5
Ascorbate	2.5
Beta-hydroxybutyrate	265
Bilirubin	20
Captopril	0.5
Cholesterol	503
Creatinine	5
Dopamine	0.1
EDTA	720
Ephedrine	10
Galactose	15
Gentisic acid	1.8
Glutathione	15
Hemoglobin	200
Heparin	6000 IU/dL
Ibuprofen	50
Icodextrin	1380
Lactate	59
Lactose	100
L-Dopa	0.6
Maltose	500
Methyl-Dopa	1.5
Parlidoxy Iodide	205
Pyruvate	10
Salicylic acid	60
Sodium	500
Tetracycline	1.5
Tolazamide	15
Tolbutamide	64
Triglycerides	1500
Uric acid	24
Xylose	45

The following is included in the "Limitations of Procedure" section of the FreeStyle Precision Neo Blood Glucose Test Strip labeling:

The system exhibits interference from Xylose at low glucose concentration levels. Do not use during xylose absorption testing.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

The performance of the FreeStyle Precision Neo Blood Glucose Test Strips with FreeStyle Libre Reader's built-in-meters was assessed with 119 participants with Type 1 or Type 2 diabetes at 2 clinical centers. Using only the instructional materials provided with the system, each participant performed fingerstick testing on the FreeStyle Libre Reader's built-in-meter. Trained operators then obtained fingerstick samples for YSI testing on the FreeStyle Libre Reader's built-in-meter. Results were analyzed by comparing the results obtained by lay users against the comparator YSI value. The range of samples tested was 34-373 mg/dL as measured by YSI. Results are summarized below.

Lay User

Glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
5/5 (100%)	5/5 (100%)	5/5 (100%)

Glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
63/114 (55.3%)	100/114 (87.7%)	110/114 (96.5%)	111/114 (97.4%)

Regression analysis

Slope	Y-intercept	R^2
1.00	-0.3	0.982

b. Matrix comparison:

Not applicable.

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):

See Section M.2.a.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

   Expected glucose values for non-diabetic, non-pregnant adults:

   Fasting: < 100 mg/dL
   Two hours after meals: < 140 mg/dL

   Source: American Diabetes Association. Classification and Diagnosis of Diabetes. 2017. Diabetes Care 40 (Suppl. 1): S11-S24.

N. Instrument Name:

FreeStyle Libre Reader's built-in-meter

O. System Descriptions:

1. Modes of Operation:

   The FreeStyle Libre Reader's built-in-meter is a component of a handheld Reader, which can be connected to a computer. The Reader can also wirelessly communicate with the Sensor as part of the FreeStyle Libre Flash Glucose Monitoring System (reviewed in P160030).

   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:

   The FreeStyle Libre Reader's built-in-meter software was reviewed in P160030 and found acceptable.

   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 device is intended to be used with capillary whole blood from the finger. The whole blood sample is applied directly to the test strip, so there are no special handling considerations.

5. Calibration:

   No calibration is required by the user.

6. Quality Control:

   The FreeStyle Precision Neo Blood Glucose Test Strips are for use with the MediSense Glucose and Ketone Control Solutions (Low, Medium, High) previously cleared under k983504. Control solutions must be purchased separately from the system.

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

1. Altitude study: 3 sets of human venous blood samples (collected into heparin tubes) were adjusted to 3 blood glucose levels: 60-70 mg/dL, 100-120 mg/dL, and 380-420 mg/dL. Each sample was measured using YSI as well as 10 FreeStyle Libre Reader's built-in-meters and 3 test strip lots at high altitude (10,000 feet) and sea level. The results support the labeling claims that altitudes up to 10,000 feet have no significant effect on performance of the FreeStyle Precision Neo Blood Glucose Test Strips with the FreeStyle Libre built-in-meter.

2. Hematocrit study: The effect of different hematocrit levels on the performance of the FreeStyle Precision Neo Blood Glucose Test Strips with the FreeStyle Libre Reader's built-in-meter was evaluated using venous whole blood samples with 15%, 20%, 30%, 42%, 50%, 60%, 65% hematocrit at glucose levels of 60-70 mg/dL, 100-120 mg/dL, 210-230 mg/dL, 330-350 mg/dL, and 440-460 mg/dL. Measurements were taken with 10 glucose meters and 3 test strip lots as well as YSI. The study supports the claimed hematocrit range of 15-65%.

3. Sample volume study: A sample volume study was performed using venous whole blood samples adjusted to 3 glucose levels (60-70 mg/dL, 100-120 mg/dL, 380-420 mg/dL). The sample volumes of 0.4 µL, 0.6 µL, and 1.0 µL were tested using 10 FreeStyle Libre Reader's built-in-meters and 3 lots of FreeStyle Precision Neo Blood Glucose Test Strips. Results of samples at each sample volume were compared to the corresponding YSI value. The study results support the claimed sample volume of 0.6 µL.

4. Operating conditions: The effect of temperature and relative humidity (RH) on the FreeStyle Precision Neo Blood Glucose Test Strips with FreeStyle Libre Reader's built-in-meter was evaluated using venous blood samples adjusted to 3 glucose levels (60-70 mg/dL, 100-120 mg/dL, 380-420 mg/dL). Measurements were taken under 5 environmental conditions (59°F/10% RH, 59°F/90% RH, 104°F/10% RH, 104°F/90% RH, 75°F/50% RH) using 10 meters and 3 lots of test strips as well as YSI. The study results support the operating condition claim of 59° to 104° F with relative humidity of 10% to 90%.

5. 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. This study was reviewed in P160030 and demonstrated complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Healthcare Bleach Germicidal Wipes (EPA Registration #67619-12). A robustness study was also conducted demonstrating that there was no change in performance or in the external materials of the meter after 156 cleaning and disinfection cycles (each cycle consisted of 1 cleaning wipe followed by 1 disinfection wipe) to simulate 3 years of device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. Electrical safety and EMC testing: Electrical safety and EMC testing of the FreeStyle Libre Reader's built-in-meter was reviewed in P160030 and found acceptable.

7. Readability assessment: A Flesch-Kincaid readability assessment demonstrated that the test strip insert was written at or below an 8th grade reading level.

8. This device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the studies in this submission were conducted prior to the finalization of the guidance documents.

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.