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

A. 510(k) Number:

K151265

B. Purpose for Submission:

New Submission

C. Measurand:

Capillary whole blood glucose from fingertip, palm, forearm, or upper arm.

D. Type of Test:

Quantitative Amperometric Assay; glucose dehydrogenase - flavin adenine dinucleotide (GDH-FAD)

E. Applicant:

SD Biosensor Inc.

F. Proprietary and Established Names:

SD GlucoNFC Blood Glucose Monitoring System

SD GlucoNFC Multi Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   862.1345, Glucose Test System

   862.1660, Quality control material (assayed and unassayed)

2. Classification:

   Class II

   Class I (reserved)

3. Product code:

   NBW - System, Test, Blood Glucose, Over-the-Counter

   LFR - Glucose Dehydrogenase, Glucose

   JJX - Single (specified) analyte controls (assayed and unassayed)

4. Panel:

   (75) Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   SD GlucoNFC Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, forearm or upper arm. SD GlucoNFC Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

   The SD GlucoNFC Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNFC Blood Glucose Monitoring System is not for use in neonates. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

   SD Gluco NFC Blood Glucose Test Strips are for use with SD GlucoNFC Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm.

   SD GlucoNavii Control Solution is intended for Quality Control of the SD GlucoNFC Blood Glucose Monitoring System. The control solution helps to check that the meter and test strips are working together properly and that the test is performing correctly..

   SD GlucoNFC Multi Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, forearm, or upper arm and venous whole blood. The SD GlucoNFC Multi 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 diabetes control program. This system should

only be used with auto-disabling, single-use lancing devices.

The SD GlucoNFC Multi Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNFC Multi Blood Glucose Monitoring System is not for use in neonates. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

SD GlucoNFC Multi Blood Glucose Test Strips are for use with SD GlucoNFC Multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm and venous whole blood.

SD GlucoNFC Multi Blood Glucose Test Strips are for use with SD GlucoNFC Multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm or upper arm, and venous whole blood.

SD GlucoNavii Control Solution is intended for Quality Control of the SD GlucoNFC Blood Glucose Monitoring System. The control solution helps to check that the meter and test strips are working together properly and that the test is performing correctly.

3. Special conditions for use statement(s):
    - For in vitro diagnostic use.
    - Do not use the system to test neonates. It has not been validated for neonatal use.
    - For the SD Gluco NFC BGMS: Critically ill patients should not be tested with this blood glucose meter.
    - For the SD GlucoNFC Multi BGMS: This device has not been evaluated in critically ill patients.
    - Not for diagnosis or screening of diabetes mellitus.
    - Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate results may occur for individuals experiencing a hyperglycemic hyperosmolar state, with or without ketosis.
    - Severe dehydration resulting from excessive water loss may cause false low results
    - Alternative site testing (AST) should only be done during steady-state times (when glucose is not changing rapidly).
    - AST should not be used to calibrate continuous glucose monitors or in insulin dose calculations.
    - For the SD GlucoNFC Multi BGMS only: For use with single-use auto-disabling lancing devices.

4. Special instrument requirements:

    SD GlucoNFC meter

    SD GlucoNFC Multi meter

I. Device Description:

SD GlucoNFC and SD GlucoNFC Multi Blood Glucose Monitoring Systems (BGMS) are over-the-counter and prescription blood glucose monitoring systems, respectively. The SD GlucoNFC BGMS is indicated for single-patient use at home and should not be shared, while the SD GlucoNFC Multi BGMS is for multi-patient use in a professional healthcare setting, in order to help monitor the effectiveness of diabetes control. The devices contain near field communication (NFC) technology.

The BGMS comes with the SD GlucoNFC or SDGlucoNFC Multi Blood Glucose Meter, one level of SD Navii Glucose Control Solution (Level 2), and SD GlucoNFC or SD GlucoNFC Multi Blood Glucose Test Strips. The SD Navii Glucose Control Solution is used to verify the performance of the SD GlucoNFC or SD GlucoNFC Multi BGMS. A second level of control (Level 3) is available for purchase separately. The device comes with a SD Glucose check strip, which is used to check the electronic performance of the meter. Use of the check strip does not take the place of running quality control solutions.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   SD GlucoMentor BGMS
   SD GlucoMentor Multi BGMS
   SD Check Gold Control Solutions

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

   K123517

3. Comparison with predicate:

Similarities		
Item	Candidate Device SD GlucoNFC K151265	Predicate Device SD GlucoMentor BGMS K123517
Intended Use	Monitoring glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm by people with diabetes at home to be used as an aid to monitor the effectiveness of diabetes control	Same
Test Time	5 seconds	Same
Measuring Range	20-600 mg/dL	Same
Test Principle	Electrochemical biosensor	Same

Similarities		
Item	Candidate Device SD GlucoNFC K151265	Predicate Device SD GlucoMentor BGMS K123517
Sample Type	Fresh capillary whole blood	Same
Sample Application	Test strip capillary draw	Same
Calibration	Plasma-calibrated	Same
Coding	none	Same
Power Source	3V CR2032 Battery x1 (Replaceable)	Same
Monitor	LCD display	Same
Backlight	No	Same
Battery Life	Approximately 1000 Tests	Same

Differences		
Item	Candidate Device SD GlucoNFC K151265	Predicate Device SD GlucoMentor BGMS K123517
Hematocrit range	10-70%	10-60%
Operating Temperature	46-113°F (8-45°C)	50-113°F (10-45°C)
Operating Humidity	10-90% RH	15-90% RH
Operating Altitude	Up to 11, 480 ft.	Up to 11,351 ft.
Sample volume	0.5 µL	0.3 µL
Test Strips	SD GlucoNFC Blood Glucose Test Strips	SD GlucoMentor Blood Glucose Test Strips
Test Strip Technology	Glucose Dehydrogenase (FAD)	Glucose Oxidase (GOD)
PC Link Feature	USB Cable or NFC Reader/Writer	USB Cable
Smart device link feature	Yes	No
Memory capacity	300 test results	500 test results
Meter Dimensions	48 mm x 90 mm x 15 mm	47 mm x 95 mm x 17.5 mm
Meter weight	50 g with battery	57.5 g with battery

Similarities		
Item	Candidate Device SD GlucoNFC Multi BGMS K151265	Predicate Device SD GlucoMentor Multi NFC K123517
Intended Use	Monitoring glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm and venous whole blood. Is	Same

Similarities		
Item	Candidate Device SD GlucoNFC Multi BGMS K151265	Predicate Device SD GlucoMentor Multi NFC K123517
	intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program.	
Test Time	5 seconds	Same
Measuring Range	20-600 mg/dL	Same
Test Principle	Electrochemical biosensor	Same
Sample Application	Test strip capillary draw	Same
Sample Type	Fresh capillary and venous whole blood	Same
Calibration	Plasma-calibrated	Same
Test Strip Storage Conditions	Temperature: 2-32°C (36-90°F) Humidity: 10-90% RH	Temperature: 2-32°C (36-90°F)
Power Source	3V CR2032 Battery x1 (Replaceable)	Same
Monitor	LCD display	Same
Backlight	No	Same
Battery Life	Approximately 1000 Tests	Same

Differences		
Item	Candidate Device SD GlucoNFC Multi BGMS K151265	Predicate Device SD GlucoMentor Multi NFC K123517
Hematocrit range	10-70%	10-60%
Operating Temperature	46-113°F (8-45°C)	50-113°F (10-45°C)
Operating Humidity	10-90% RH	15-90% RH
Operating Altitude	Up to 11, 480 ft.	Up to 11,351 ft.
Sample volume	0.5 µL	0.3 µL
Test Strips	SD GlucoNFC Multi Blood Glucose Test Strips	SD GlucoMentor Multi Blood Glucose Test Strips
Test Strip Technology	Glucose Dehydrogenase (FAD)	Glucose Oxidase (GOD)
PC Link Feature	USB Cable or NFC Reader/Writer	USB Cable
Smart device link feature	Yes	No
Memory capacity	300 test results	500 test results
Meter Dimensions	48 mm x 90 mm x 15 mm	47 mm x 95 mm x 17.5 mm

Differences		
Item	Candidate Device SD GlucoNFC Multi BGMS K151265	Predicate Device SD GlucoMentor Multi NFC K123517
Meter weight	50 g with battery	57.5 g with battery

Similarities and differences of the control solution		
	Candidate Device SD GlucoNavii Control Solution	Predicate Device SD Check Gold Control Solution, k123517
Matrix	Viscosity-adjusted, aqueous liquid.	Same
Levels	Level 2 and Level 3	Level M and Level H

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

CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline–Second Edition
CLSI EP6-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
IEC 61010-1:2001, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements (Second Edition)
IEC 61010-2-101:2002, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61326-2-6:2005, Electrical equipment for measurement, control and laboratory use – EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
IEC 60068-2-64:2008, Environmental testing – Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance
ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices

L. Test Principle:

The SD GlucoNFC and SD GlucoNFC Multi Blood Glucose Monitoring Systems use an amperometric biosensor technology to measure the glucose level in human blood. The reaction between glucose and the materials contained in the test strip, GDH-FAD, and potassium ferrocyanide, results in an electrical current. The glucose concentration is calculated from this current.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   Performance testing was conducted on the SD GlucoNFC Blood Glucose Meter only. This is acceptable because the only differences between the SD GlucoNFC and SD GlucoNFC Multi BGMS are the name and intended use (single-patient vs. multiple-patient use).

   a. Precision/Reproducibility:

   Repeatability:
   Venous blood was spiked with five different glucose concentrations (30-50, 51-110, 111-150, 151-250, and 251-400mg/dL) and tested on ten SD GlucoNFC meters and three lots of test strips. Ten replicates were tested per meter per glucose concentration. The results from all strip lots are summarized below:

Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	100	48.8	1.0	2.0
	2	100	48.8	1.1	2.3
	3	100	48.9	1.0	2.1
51-110	1	100	82.9	2.0	2.5
	2	100	82.7	2.0	2.4
	3	100	82.5	1.8	2.2
111-150	1	100	143.6	4.8	3.3
	2	100	143.7	3.7	2.5
	3	100	143.6	3.8	2.6
151-250	1	100	223.6	6.6	3.0
	2	100	222.6	7.2	3.2
	3	100	223.9	7.1	3.2
251-400	1	100	333.9	8.2	2.5
	2	100	333.0	7.3	2.2
	3	100	334.4	7.2	2.2

   Intermediate Precision:

   Intermediate Precision was evaluated using three lots of test strips and ten SD GlucoNFC meters. Three levels of Glucose control solutions were used. For each level of control, ten replicates were taken each day for ten days, so that 100 individual measurements were generated per control level. The results from all strip lots are summarized below:

Control Level	Strip Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	1	100	62.4	1.5	2.4
	2	100	62.6	1.3	2.1
	3	100	62.5	1.5	2.3
Level 2	1	100	136.1	3.3	2.4
	2	100	136.9	3.5	2.5
	3	100	136.6	3.4	2.5
Level 3	1	100	232.6	8.6	3.7
	2	100	233.1	8.2	3.5
	3	100	233.6	7.0	3.0

b. *Linearity/assay reportable range:*

The claimed measuring range for this device is 20-600mg/dL. Linearity was evaluated using three lots of test strips, five SD GlucoNFC meters and 11 venous whole blood samples with the following glucose concentrations: 16.8, 39.3 60.4, 86.4 119.5156.8, 227.3, 299.3, 367.8, 436.5, 512.5, 573.8, 647.3, and 720.3 mg/dL, obtained by spiking with glucose solution. Each glucose level was analyzed 5 times on each meter. Linear regression analysis for each meter compared to results obtained using YSI resulted in the following:

Lot 1: $y = 0.999x – 0.199$; $R2 = 0.998$
Lot 2: $y = 0.994x + 1.007$; $R2 = 0.998$
Lot 3: $y = 0.986x + 2.394$; $R2 = 0.997$

The results of the study support the sponsor's claimed glucose measurement range of 20-600 mg/dL.

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

The SD GlucoNFC and SD GlucoNFC Multi systems are traceable to the NIST SRM 917c reference material. The method comparison study was performed using the YSI 2300 Glucose analyzer as the reference method (see Section M.2.a.)

Test strip stability:

Real time closed and open vial stability for the SD GlucoNFC and SD GlucoNFC Multi blood glucose test strips were assessed in real-time studies. Study protocols and acceptance criteria were reviewed and found acceptable to support the sponsor's claimed closed vial (shelf life) stability of 24 months, and open vial stability of 6 months when stored under the recommended storage conditions of 36°F to 90°F (2-32°C) and relative humidity of 10-90%.

Control solution stability:

Real time closed and open vial stability for the control solutions were assessed in real-time testing Protocols and acceptance criteria were reviewed and found acceptable to support the sponsor's claimed closed vial (shelf life) stability of 24 months, and open vial stability of 3 months when stored at the recommended storage temperature of 46-86°F (8-30°C).

Value assignment of controls:

Three targeted concentrations of the controls are prepared gravimetrically and analyzed using the YSI 2300 STAT Plus. Each level of the control solution is tested 40 times. The mean along with SD and CV are used to establish the ranges for each level which are then provided on the test strip vial label.

d. Detection limit:

The measuring range of the device is 20-600 mg/dL. This range is validated via linearity study. See section M.1.b.

e. Analytical specificity:

The sponsor performed interference studies with spiked venous blood samples at 2 different glucose concentrations (YSI reference values of 65 and 250mg/dL). The samples were divided into 4 groups (1 control and 3 test conditions with 3 different levels of interferent). Each sample was measured twice by the reference method and once with five GlucoNFC meters per glucose concentration. The sponsor defines no significant interference as bias < ± 10% for the test compared to control samples. The following table lists the concentrations of each substance at which no significant interference was detected.

Potential Interferent	Highest concentration tested at which no significant interference is observed (mg/dL)
Acetaminophen	6
Ascorbic acid	4
Bilirubin	35
Uric acid	5
Triglyceride	1500
Total Cholesterol	500
Acetyl-salicylic acid	120
Ibuprofen	50
Fructose	15
Tetracycline	5
Tolbutamide	100
Dopamine	2.5

Methyl-dopa	2
Creatinine	30
Urea	500
Tolazamide	5
Warfarin	2
Levodopa	4
Maltotetraose	120
Mannose	5
Lactose	25
Mannitol	800
Sorbitol	10
Xylitol	25
Sodium salicylate	70
Xylose	30
Maltotriose	240
Hemoglobin	200
Gentistic acid	500
Glutathione	12.5
Galactose	60
Ethanol	400
Maltose	500

To address potential interference from acetaminophen ≥ 6 mg/dL, ascorbic acid ≥ 4 mg/dL, uric acid ≥ 5 mg/dL, and xylose ≥ 30 mg/dL, the labeling contains the following statements:

> If you are taking acetaminophen containing drugs (e.g. Tylenol), Vitamin C (ascorbic acid), you may get inaccurate results.
>
> If you have a disease or condition in which uric acid levels in your blood may be elevated, such as gout, you may get inaccurate results with this system.

This system should not be used when undergoing xylose absorption tests.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
System Accuracy was assessed in a study using ten SD GlucoNFC meters and three lots of test strips. Results from the meter were compared to results from the reference method, YSI. Samples from the finger, palm, forearm, and upper arm of 115 participants were collected. The total range of samples tested was from 27.5 – 510 mg/dL. To achieve glucose concentrations less than 50 mg/dL, 5 finger samples were

allowed to glycolize. To achieve glucose concentrations greater than 400 mg/dL, 5 finger samples were spiked. Results of the meter measurements relative to YSI are summarized below:

	Glucose concentrations <75 mg/dL		
Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger	14/20 (70%)	20/20 (100%)	20/20 (100%)
Palm	10/15 (66.7%)	15/15 (100%)	15/15 (100%)
Forearm	10/15 (66.7%)	15/15 (100%)	15/15 (100%)
Upper arm	10/15 (66.7%)	15/15 (100%)	15/15 (100%)

	Glucose concentrations ≥75 mg/dL			
Site	Within ± 5 %	Within ± 10%	Within ± 15%	Within ± 20%
Finger	50/100 (50%)	90/100 (90%)	100/100 (100%)	100/100 (100%)
Palm	46/95 (48.4%)	86/95 (90.5%)	95/95 (100%)	95/95 (100%)
Forearm	45/95 (47.4%)	86/95 (90.5%)	95/95 (100%)	95/95 (100%)
Upper arm	39/95 (41.1%)	84/95 (88.4%)	95/95 (100%)	95/95 (100%)

Linear regression results:

	Finger	Palm	Forearm	Upper arm
Slope	0.9883	0.9841	0.9875	0.9853
Y-intercept	2.6706	1.3877	1.0614	1.7441
R	0.9953	0.9936	0.9933	0.9917
R^2	0.9907	0.9873	0.9866	0.9834

b. *Matrix comparison:*

Venous whole blood samples from 120 volunteers were collected into sodium heparin tubes. The blood glucose concentration was first measured by YSI, then the blood glucose concentration was tested using three lots of test strips on 15 SD GlucoNFC meters. The total range of samples tested was 25.9 – 513 mg/dL. To achieve concentrations of glucose <50 mg/dL, 5 samples were allowed to glycolyze. To achieve concentrations of glucose >400 mg/dL, 5 samples were spiked. The results relative to the reference, YSI, are summarized below:

	Glucose concentrations <75 mg/dL		
Venous Blood	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
	18/24 (75%)	24/24 (100%)	24/24 (100%)

Glucose concentrations ≥75 mg/dL			
Within ± 5 %	Within ± 10%	Within ± 15%	Within ± 20%
57/96 (59.4%)	89/96 (92.7%)	96/96 (100%)	96/96 (100%)

Linear Regression results:

Slope	Y-intercept	R	R2
0.9922	1.0430	0.9958	0.9917

An additional study was done to support use of the device with venous whole blood when collected with additional anticoagulants. The sponsor collected venous blood samples from 100 volunteers into 4 separate tubes, containing sodium heparin, lithium heparin, EDTA-K2 and EDTA-K3, using 3 test strip lots. The total range of samples tested was 38 to 475 mg/dL. To achieve glucose concentrations < 50 mg/dL and > 400 mg/dL samples were spiked and allowed to glycolyze. The meter results relative to the reference, YSI, are summarized below:

Sodium heparin vs. reference

Glucose concentration <75 mg/dL			**Glucose concentration ≥75 mg/dL**			
Within ±5mg/dL	Within ±10mg/dL	Within ± 15 mg/dL	Within ± 5 %	Within ± 10%	Within ± 15%	Within ± 20%
12/16 (75.0%)	16/16 (100%)	16/16 (100%)	50/84 (59.5%)	84/84 (100%)	84/84 (100%)	84/84 (100%)

Lithium heparin

Glucose concentration <75 mg/dL			**Glucose concentration ≥75 mg/dL**			
Within ±5mg/dL	Within ±10mg/dL	Within ± 15 mg/dL	Within ± 5 %	Within ± 10%	Within ± 15%	Within ± 20%
15/16 (93.8%)	16/16 (100%)	16/16 (100%)	58/84 (69.0%)	81/84 (96.4%)	84/84 (100%)	84/84 (100%)

EDTA-K2

Glucose concentration <75 mg/dL			**Glucose concentration ≥75 mg/dL**			
Within ±5mg/dL	Within ±10mg/dL	Within ± 15 mg/dL	Within ± 5 %	Within ± 10%	Within ± 15%	Within ± 20%
13/16 (81.3%)	16/16 (100%)	16/16 (100%)	61/84 (72.6%)	82/84 (97.6%)	84/84 (100%)	84/84 (100%)

EDTA-K3

Glucose concentration <75 mg/dL			**Glucose concentration ≥75 mg/dL**			
Within ±5mg/dL	Within ±10mg/dL	Within ± 15 mg/dL	Within ± 5 %	Within ± 10%	Within ± 15%	Within ± 20%
15/16 (93.8%)	16/16 (100%)	16/16 (100%)	66/84 (78.6%)	82/84 (97.6%)	84/84 (100%)	84/84 (100%)

Linear regression results:

	Na heparin	Li heparin	EDTA-K2	EDTA-K3
slope	0.9907	1.0007	1.0025	1.0012
Y- intercept	-0.1967	-0.7063	-0.8310	-1.3730
R	0.9946	0.9955	0.9974	0.9968
R^2	0.9892	0.9910	0.9949	0.9936

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):

A lay user study was conducted at three sites using only English speaking and reading participants. A total of 120 subjects participated in these studies. Three test strip lots were used to evaluate the accuracy between results obtained from the fingertip and the alternative sites testing (AST) using SD GlucoNFC BGMS and the YSI results. Each participant was given the Instructions for Use guide only, with no additional coaching or instruction provided.

Each subject collected fingerstick and AST (palm, forearm, upper arm) samples and tested using the NFC meter. After self-testing, the healthcare professional measured the blood glucose concentration from new fingerstick and alternative site punctures using the YSI only. After each procedure, the subjects were asked to answer a questionnaire evaluating their understanding of the procedures. The range of glucose values for the finger stick samples was 62 - 416 mg/dL as measured by the reference, YSI. The results are summarized below:

	Glucose concentrations <75 mg/dL		
Site	Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
Finger	9/15 (60.0%)	15/15 (100%)	15/15 (100%)
Palm	9/15 (60.0%)	15/15 (100%)	15/15 (100%)
Forearm	9/15 (60.0%)	15/15 (100%)	15/15 (100%)
Upper arm	9/15 (60.0%)	15/15 (100%)	15/15 (100%)

	Glucose concentration ≥75 mg/dL			
Site	Within ± 5 %	Within ± 10%	Within ± 15%	Within ± 20%
Finger	50/105 (47.6%)	97/105 (92.4%)	105/105 (100%)	105/105 (100%)
Palm	53/105 (50.5%)	93/105 (88.6%)	105/105 (100%)	105/105 (100%)
Forearm	52/105(49.5%)	93/105 (88.6%)	105/105 (100%)	105/105 (100%)
Upper arm	52/105 (49.5%)	93/105 (88.6%)	105/105 (100%)	105/105 (100%)

Linear Regression results:

Tested by lay-user				
Site	Fingerstick	Palm	Forearm	Upper arm
Slope	0.9876	0.9847	0.9860	0.9842
Y-intercept	1.8072	2.5201	1.8486	2.8443
R	0.9971	0.9954	0.9957	0.9947
R^2	0.9942	0.9919	0.9913	0.9895

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

The fasting adult blood glucose range for a person without diabetes[1]:

- Before meals <100 mg/dL (5.6 mmol/L)
- After meals: <140 mg/dL (7.8 mmol/L)

[1]American Diabetes Association: Clinical Practice Recommendations (2015. Diabetes Care, Vol 38, Supplement 1, p. S8-S16.

N. Instrument Name:

SD GlucoNFC Blood Glucose Meter
SD GlucoNFC Multi Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   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:

   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, palm, forearm, and upper arm. The SD GlucoNFC Multi BGMS may also be used with venous whole blood. The whole blood sample is applied directly to the test strip by capillary action therefore there are no special handling or storage issues.

5. Calibration:

   This is a non-coding device, therefore no calibration is required by the user.

6. Quality Control:

   Each SD GlucoNFC Multi BGMS comes with one level of SD GlucoNavii Control Solution (Level 2). The control solution is used to check if the meter and test strips as a

system are working normally, or if the user is performing the test correctly. Control solution tests should be performed when a new box of test strips is opened, the test strip container is left open or the test strips are damaged, if the strips are left in extreme temperature or humidity, if the patient wants to check the meter and test strips, whenever the meter is dropped, whenever a result does not agree with the level felt by the patient or the patient wants to check if they are testing correctly.

Each system includes a SD Glucose check strip, which is used to check the electronic performance of the meter. The check strip may be used before using the meter for the first time, or after a long period of disuse of the meter. The check strip test does not replace the Control Solution test.

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

1. **Altitude study:** An altitude study was performed in a barometric pressure test chamber to simulate the following 4 different altitudes: sea level, 3,280 ft, 6,561ft, and 11,480 ft. Venous blood was spiked with glucose to achieve three glucose concentrations (45.5 mg/dL, 112 mg/dL and 348 mg/dL, as measured by YSI). Each sample was tested in duplicate with 5 meters and the results were compared to YSI. The results demonstrate acceptable bias to the reference to support the claims that altitudes up to 11,480 feet have no significant effect on blood glucose measurements with the SD GlucoNFC and SD GlucoNFC Multi Blood Glucose Monitoring Systems.

2. **Hematocrit study:** The effect of different hematocrit levels were evaluated using venous whole blood samples with hematocrit levels of 10%, 20%, 30%, 50%, 60%, 70%, and 75%, spiked to five glucose concentrations (42, 68, 92, 128, and 360 mg/dL, as measured by YSI). The samples were tested with 10 meters and three lots of test strips. The results were compared to YSI and the normal 40% hematocrit. The percent bias of the SD GlucoNFC meter results relative to YSI demonstrated adequate performance to support the claimed hematocrit range of 10-70%.

3. **Infection control studies:** The SD GlucoNFC meter is intended for single-patient use, and the SD GlucoNFC Multi meter is intended for multiple-patient use. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial laboratory service to demonstrate complete inactivation of hepatitis B virus (HBV) with DisCide Ultra Disinfecting Towelettes (EPA Reg. No. 10492-4). Robustness studies were performed by the sponsor demonstrating that there was no change in performance or in external materials of the meter after 10,950 cleaning and disinfection cycles with DisCide Ultra Disinfecting Towelettes. The robustness studies were designed to simulate 3 years of multiple-patient use and 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

4. **Sample volume study:** A sample volume study was performed using venous whole blood samples spiked to three levels of glucose concentrations (50 mg/dL, 110 mg/dL

and 220 mg/dL, as measured by YSI) to evaluate the effect of different sample volumes (0.2 µL, 0.3 µL, 0.4 µL, 0.5 µL, 0.6 µL, 0.8 µL, and 1.0 µL) on the performance of the device. Results at each sample volume were compared to the corresponding YSI values. Two lots of test strips and 10 meters were used. Results from these studies support the claimed minimum sample volume of 0.5 µL. The meter displays error message E-2 when an insufficient amount of blood sample is applied. The sponsor provided adequate validation for this error message.

5. **Operating Temperature and Humidity:** Operating temperature and humidity conditions were evaluated using six meters and three lots of test strips with venous whole blood samples at three glucose concentrations (55 mg/dL, 110 mg/dL, and 300 mg/dL by YSI). The following temperature and humidity conditions were tested: 46°F (8°C)/10% RH, 46°F (8°C)/90% RH, 113°F (45°C)/10%RH, and 113°F (45°C)/90% RH. The results support the sponsor's claimed operating temperature from 46°F to 113°F (8°C - 45°C) and relative humidity range from 10-90%.

6. **EMC testing and Electrical Safety Studies:** The sponsor states that they followed requirements of IEC 61010-1:2001, IEC61010-2-101:2002, and IEC 61326-2-6:2005. The sponsor provided documentation stating that the SD GlucoNFC and SD GlucoNFC Multi meters were found to be in compliance with the test standards IEC 61010-1:2001, IEC61010-2-101:2002, and IEC 61326-2-6:2005.

7. **Readability Assessment:** A Flesch-Kinkaid reading level assessment was conducted demonstrating that the user manuals and test strip inserts were written at or below an 8th grade reading level.

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.