

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

A. 510(k) Number:

k132929

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood from the finger, palm, forearm, and upper arm

D. Type of Test:

Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:

SD Biosensor Inc.

F. Proprietary and Established Names:

SD GlucoNavii Mentor NFC Blood Glucose Monitoring System
SD GlucoNavii Mentor NFC multi Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

862.1345, Glucose Test System

2. Classification:

Class II

3. Product code:

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

CGA- Glucose test system

4. Panel:

(75) Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

SD GlucoNavii® Mentor NFC Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, upper arm, or forearm. SD GlucoNavii® Mentor NFC 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 GlucoNavii® Mentor NFC Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNavii® Mentor NFC 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 GlucoNavii® Mentor NFC Blood Glucose Monitoring System is intended to be used to transmit glucose values to compatible mobile application on PC software through use of radio frequency communication.

The SD GlucoNavii® Mentor NFC Blood Glucose Test Strips are for use with the SD GlucoNavii® Mentor NFC Blood Glucose Meter to quantitatively measure glucose (sugar) fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm.

SD GlucoNavii® Mentor NFC 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, upper arm, or forearm. The SD GlucoNavii® Mentor NFC 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 GlucoNavii® Mentor NFC Multi Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNavii® Mentor NFC 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 GlucoNavii® Mentor NFC Blood Glucose Monitoring System is intended to be used to transmit glucose values to compatible mobile application on PC software

through use of radio frequency communication.

The SD GlucoNavii® Mentor NFC Multi Blood Glucose Test Strips are for use with the SD GlucoNavii® Mentor NFC Multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm.

3. Special conditions for use statement(s):

- For In Vitro Diagnostic Use only
- Do not use for screening or diagnosis of diabetes mellitus.
- Not for use in the critically ill.
- Not intended for use on neonates.
- Not to be used for individuals who are dehydrated, hypertensive, hypotensive or in shock.
- Not for use in hyperosmolar patients
- AST should not be used to calibrate CGMs or in insulin dose calculation.
- AST should only be used during periods of steady state blood glucose conditions.

4. Special instrument requirements:

SD GlucoNavii Mentor NFC meter
SD GlucoNavii Mentor NFC Multi meter

I. Device Description:

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

The meter comes with near field communication (NFC). NFC is a set of standards for smart devices to establish radio communication with each other by touching them together or bringing them into close proximity. This function is compatible for test results back-up on PC or smart devices.

The BGMS comes with one level of SD Glucose Control Solution (Level M previously cleared in k123517) and SD GlucoMentor Test Strips or SD GlucoMentor Multi Test Strips. The SD Glucose Control Solutions are used to verify the performance of the SD GlucoNavii Mentor BGMS. The device comes with a SD Glucose check strip which is used to check the performance of the meter, before using the meter for the first time, whenever a result does not agree with the level felt by the patient or if the patient has repeated a test and the blood glucose result is still lower or higher than expected.

J. Substantial Equivalence Information:

1. Predicate device name(s):
SmartLink Gold
2. Predicate 510(k) number(s):
k100398
3. Comparison with predicate:

Similarities			
Item	Candidate Device SD GlucoNavii Mentor NFC BGMS k132929	Candidate Device SD GlucoNavii Mentor NFC Multi BGMS k132929	Predicate Device SmartLink GOLD BGMS k100398
Intended use	It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes as an aid to monitor the effectiveness of diabetes control.	It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes as an aid to monitor the effectiveness of diabetes control.	same
Detection Method	Glucose Oxidase biosensor	Glucose Oxidase biosensor	same
Measuring range	20-600mg/dL	20-600mg/dL	same
Hematocrit range	20-60%	20-60%	Same
Sample Type	Fresh capillary whole blood from fingertips	Fresh capillary whole blood from fingertips	same
Alternate site testing (AST)	Palm, forearm, upper arm	Palm, forearm, upper arm	Same
Operating temperature range	50°F-113°F (10°C-45°C)	50°F-113°F (10°C-45°C)	same
Humidity	15-95%	15-95%	Same
Altitude	Up to 11,351feet	Up to 11,351feet	Same
Test time	5 seconds	5 seconds	Same
Power source	3V CR2032 battery	3V CR2032 battery	Same
PC connection/transmission function	USB cable	USB cable	Same
Voice feature	No	No	No
Test strip storage	36-90°C 10-95% RH	36-90°C 10-95% RH	Same

Differences			
Item	Candidate Device SD GlucoNavii Mentor NFC BGMS k132929	Candidate Device SD GlucoNavii Mentor NFC Multi BGMS k132929	Predicate Device SmartLink GOLD BGMS k100398
Sample Volume	0.3uL	0.3uL	0.9uL

Differences			
Item	Candidate Device SD GlucoNavii Mentor NFC BGMS k132929	Candidate Device SD GlucoNavii Mentor NFC Multi BGMS k132929	Predicate Device SmartLink GOLD BGMS k100398
Dimensions	50mm x 93mm x 18m	50mm x 93mm x 18m	47mm x 95mm x 17.5mm
Memory	300 test results	300 test results	400 test results
Meter Weight	50g with battery	50g with battery	47.5g with battery
Test strips	SD GlucoMentor™ NFC Blood Glucose Test Strips	SD GlucoMentor™ NFC Multi Blood Glucose Test Strips	SmartLink Gold Test Strip

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

- ISO14971:2007: Medical devices - Applications of risk management to medical devices
- CLSI EP05-A2: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition
- CLSI EP09-A2: 2004: Method Comparison and Bias Estimation Using Patient Samples
- IEC 60601-1-2 EDITION 3: 2007-03, Medical Electrical Equipment-Part 1-2: General Requirements for basic safety and essential performance-collateral standard: electromagnetic capability-requirements and tests (General II IES/EMS)

L. Test Principle:

SD GlucoNavii® Mentor NFC and NFC Multi Blood Glucose Monitoring Systems are electronic devices that utilize the amperometric biosensor technology for measuring the glucose level in human blood. A drop of blood sample from the finger prick works with glucose oxidase and the mediators in the test strip to make a small electric current proportional to the glucose concentration in the blood. The meter reads the current and displays the blood glucose result equivalent to the current. Within five seconds, the level of blood glucose will be shown on the digital display screen.

M. Performance Characteristics (if/when applicable):

1. Analytical performance: Performance testing was conducted on the SD GlucoNavii Mentor NFC meter as the GlucoNavii Mentor NFC Multi meter is the same meter and share the same performance. The only difference is in the intended user.

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 10 SD GlucoNavii Mentor NFC meters and 4 lots of test strips. Ten replicates were tested per meter per glucose concentration. The results from one representative lot are

summarized below:

Glucose Concentration	N	Mean (mg/dL)	SD (mg/dL)	%CV
30-50	100	53.4	1.4	2.4
51-110	100	87.9	1.7	1.9
111-150	100	133.7	3.2	2.4
151-250	100	203.8	3.9	1.9
251-400	100	328.4	5.9	1.8

Intermediate Precision

Intermediate Precision was evaluated using three lots of test strips and ten SD GlucoNavii NFC meters. Glucose control solutions in three concentration ranges were used (55-85, 88-132, 264-396mg/dL). 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:

Original study

Control Level (mg/dL)	N	Mean (mg/dL)	SD (mg/dL)	%CV
Level L	100	70.6	2.98	4.2
Level M	100	113.1	3.9	3.4
Level 3H	100	332.6	13.2	3.98

b. Linearity/assay reportable range:

The claimed measuring range for this device is 20-600mg/dL. Linearity was evaluated using 3 lots of test strips, 5 SD GlucoNavi Mentor NFC meters and 13 venous whole blood samples with the following glucose concentrations: 16.6, 22.1, 54.3, 86.4, 157.5, 227.3, 297.5, 368.3, 438.8, 509.3, 579.3, 649.8 and 719.8mg/dL, obtained by spiking with glucose solution. Each glucose level was analyzed 5 times on each meter. The sponsor states that the 5 SD GlucoNavii Mentor NFC meters are specially designed having an unlimited possible range of measurement; however, will read Lo for values under 20mg/dL and HI for values greater than 600mg/dL. Linear regression analysis compared to YSI resulted in the following:

Lot 1: $y=1.011x - 1.964; R^2=0.999$
 Lot 2: $y=1.006x - 1.202; R^2=0.999$
 Lot 3: $y=1.008x - 2.159; R^2=0.999$
 Combined: $y=1.009x - 1.775; R^2=0.999$

The study results support the claimed measuring range of 20-600mg/dL.

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

Traceability:

The traceability for the SD GlucoNavii Mentor NFC Blood Glucose Monitoring system is traceable to the NIST SRM 917b reference material. The method

comparison study was performed using the candidate device and YSI as the reference method.

Test strip stability:

When stored at the recommended storage temperature of 36°F to 90°F and the relative humidity of 10-95%, the unopened shelf-life is 24 months and once opened, the test strips are stable for up to 6 months.

Control solution stability:

Control solution stability previously established in k100398. The unopened shelf-life for the control solutions is 24 months at the recommended storage of 46°F to 86°F. Once opened, the control solutions are stable for 3 months when stored at 46°F to 86°F.

Value assignment:

Value assignment for the controls was previously established in k100398.

d. Detection limit:

The measuring range of the device is 20-600mg/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 (65 and 250mg/dL). The samples were divided into 4 groups (1 control/non-treated and 3 treated). Each sample was measured twice by the reference method and once with 10 GlucoNavii Mentor NFC meters and one lot of test strips. The following table lists the concentrations of each substance at which no significant interference was detected.

Potential Interferent	Concentration at which no significant interference is observed (mg/dL)
Acetaminophen	6
Ascorbic acid	4
Ibuprofen	50
Methyl dopa	2
Dopamine	2.5
Tolbutamide	100
Bilirubin	35
Triglyceride	1500
Uric acid	5
Creatinine	30
Hemoglobin	200
Total Cholesterol	500

Acetylsalicylic acid	120
Fructose	15
Galactose	60
Tetracycline	5
Urea	500
Tolazamide	5
Warfarin	1
Levodopa	4
Sodium Fluoride	200
Maltotetraose	120
Mannose	5
Lactose	25
Mannitol	800
Sorbitol	10
Xylitol	25
Maltose	500
Sodium salicylate	63
Xylose	50
Maltotriose	240
EDTA	200
Gentisic acid	1.8
Glutathione	4.6
Ethanol	400
Heparin	3000 IU/L

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

a. Method comparison with predicate device:

System Accuracy

System Accuracy was performed on 10 SD GlucoNavii Mentor NFC meters and 4 lots of test strips over 10 days. Two hundred twenty (220) fresh capillary samples from finger punctures ranging from 26-464mg/dL and 100 fresh samples from the palm, forearm and upper arm were collected and measured on two meters followed by YSI. To achieve glucose concentration less than 50mg/dL, 6 samples were glycolyzed. To achieve glucose concentration greater than 400mg/dL 6 samples were spiked. Linear regression analysis is listed below. Results of singlicate measurements are listed below.

	Finger	Palm	Forearm	Upper arm
Slope	1.0447	1.0269	1.0282	1.0373
y-intercept	-0.2241	1.2776	1.2533	-0.1094
R	0.9952	0.9974	0.9975	0.9977

SD GlucoNavii Mentor NFC meter							
Glucose concentration <75mg/dL				Glucose Concentration ≥75mg/dL			
Site	Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Finger	19/32 59.4%	28/32 87.5%	31/32 96.9%	109/188 58.0%	156/188 83.0%	179/188 95.2%	186/188 98.9%
Palm	8/16 50.0%	16/16 100%	16/16 100%	51/84 60.7%	70/84 83.3%	81/84 96.4%	84/84 100%
Forearm	9/16 56.3%	16/16 100%	16/16 100%	51/84 60.7%	68/84 81.0%	81/84 96.4%	84/84 100%
Upper arm	9/16 56.3%	16/16 100%	16/16 100%	51/84 60.7%	68/84 81.0%	80/84 95.2%	84/84 100%

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):*

User Performance Study:

Evaluation of the use of the device in the hands of the intended users was conducted using only English speaking and reading participants. A total of 311 total subjects participated in these studies. Three different test strip lots were used to evaluate the accuracy between results obtained from the fingertip and alternative sites using SD GlucoNavii Mentor NFC BGMS to the YSI results. Each participant was given the Instructions for use guide, control solution and check strip. Each participant performed calibration and quality control procedures using the control solution and check strip without assistance by healthcare professionals. After each procedure, the subjects were asked to answer the questionnaire evaluating their understanding of the

procedures. Each subject collected and tested a fingerstick and 3 AST (palm, forearm, upper arm) samples using the NFC meter. After self-testing, the healthcare professional collected blood from the same participant's finger capillary and measured the blood glucose using both YSI and SD GlucoNavii Mentor NFC meter. The range of glucose values for the finger stick samples was 67.8-425mg/dL measured by YSI. Results are summarized below:

All SD GlucoNavii Mentor NFC meter results vs. Reference

	Tested by Professional (finger)	Tested by lay-user			
		Finger	Palm	Forearm	Upper arm
Slope	1.0923	1.0118	1.0632	1.0804	1.0596
y-intercept	-7.1251	3.2445	-2.7436	-4.2085	-2.5655
R	0.9855	0.9873	0.9803	0.9836	0.9899

For glucose concentrations <75mg/dL

Sample site	Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
Finger	8/13 61.5%	13/13 100%	13/13 100%
Palm	4/13 30.8%	12/13 92.3%	13/13 100%
Forearm	7/13 53.8%	13/13 100%	13/13 100%
Upper Arm	7/13 53.8%	13/13 100%	13/13 100%

For glucose concentrations ≥75mg/dL

Sample site	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Finger	153/298 51.3%	248/298 83.2%	285/298 95.6%	296/298 99.3%
Palm	149/298 50%	221/298 74.2%	269/298 90.3%	290/298 97.3%
Forearm	148/298 49.7%	227/298 76.2%	271/298 90.9%	287/298 96.3%
Upper arm	154/298 51.7%	245/298 82.2%	287/298 96.3%	298/298 100%

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The fasting adult blood glucose range for a person without diabetes¹:

- Before meals < 100 mg/dL
- After meals < 140 mg/dL

N. Instrument Name:

SD GlucoNavii® Mentor NFC blood glucose meter
SD GlucoNavii® Mentor NFC Multi 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. The minimal sample volume is 0.3µL.

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

6. Quality Control:

Each kit comes with SD Glucose Control Solution Level M. The control solution is used to check that the meter and test strips are working together as a system and that 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 contains a SD Glucose check strip which is used to check the performance of the meter, before using the meter for the first time, whenever a result does not agree with the level felt by the patient or if the patient has repeated a test and the blood glucose result is still lower or higher than expected.

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

- 1. Altitude study:** An altitude study was performed at the following 4 different altitudes: 328 feet (100m), 3280 feet (1000m), 6561 feet (2000m) and 11,351 feet (3460m) with venous blood samples with glucose concentrations ranging from 43mg/dL to 352mg/dL. Each sample was tested in duplicate with 5 meters and one test strip lot and the results were compared to YSI. The results demonstrate acceptable bias to the reference to support the claims in the labeling that altitudes up to 11,351 feet have no significant effect on blood glucose measurements from the GlucoNavii Mentor NFC Monitoring System.
- 2. Hematocrit study:** The effect of different hematocrit levels were evaluated using venous whole blood samples with hematocrit levels of 15-65% (15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65%) spiked with three levels of glucose concentrations (60, 150, 350mg/dL). 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 GlucoNavii Mentor NFC meters results relative to YSI demonstrated adequate performance to support the claimed hematocrit range of 20-60%.
- 3. Infection control studies:**

The SD GlucoNavii Mentor NFC meter is intended for single patient use and the SD GlucoNavii Mentor NFC multi meter is intended for multiple patient use. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial laboratory testing 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 external materials of the meter after 10,950 cleaning and 10,950 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:** A sample volume study was performed using five venous whole blood samples ranging from 58-240mg/dL to evaluate effect of different sample volumes (0.1µL, 0.2µL, 0.3µL, 0.4µL, 0.5µL, 0.6µL, 0.8µL, 1.0µL) 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 sample volume of 0.3µL. The meter displays error message E-2 when an insufficient amount of blood sample is applied. This error message feature has been validated.

5. **Operating Temperature and Humidity:** Temperature and humidity operating conditions were evaluated using 6 SD GlucoNavii Mentor NFC meters and three lots of test strips with venous whole blood samples at three glucose concentrations (49.3mg/dL, 110.3mg/dL and 312mg/dL). The meters were exposed to the following temperature and humidity ranges 50°F/15%RH, 50°F/95%RH, 80°F/15%RH, 80°F/95%RH, 113°F/15% and 113°F/95%RH. Protocol and acceptance criteria were provided and found to be acceptable. The results supported the sponsor's claimed operating temperature from 50°F to 104°F and relative humidity range from 15% - 95%.
6. **Risk Management:** The sponsor states that they followed the requirements in ISO14971:2003 and ISO14971:2007 to assess the risk of their device
7. **EMC testing and Electrical Safety Studies:** The sponsor provided documentation certifying that acceptable electromagnetic testing (EMC) had been performed and the GlucoNavii Mentor NFC and GlucoNavii Mentor NFC Multi were found to be in compliance.
8. **Readability Assessment:** A Flesch-Kinkaid reading level assessment was conducted of the SD GlucoNavii Mentor NFC Blood Glucose Monitoring System User instruction guide, giving a readability grade level of 7.5.

A Flesch-Kinkaid reading level assessment was conducted of the SD GlucoNavii Mentor NFC Multi Blood Glucose Monitoring System User instruction guide, giving a readability grade level of 7.9.

A Flesch-Kinkaid reading level assessment was conducted of the SD GlucoNavii Mentor NFC Blood Glucose Test Strip Package Insert, giving a readability grade level of 6.2.

A Flesch-Kinkaid reading level assessment was conducted of the SD GlucoNavii Mentor NFC Multi Blood Glucose Test Strip Package Insert, giving a readability grade level of 6.9.

A Flesch-Kinkaid reading level assessment was conducted of the SD Glucose Control Solution Package Insert, giving a readability grade level of 6.9.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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