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

A. 510(k) Number:

k160742

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose oxidase (Aspergillus sp.)

E. Applicant:

i-SENS, Inc.

F. Proprietary and Established Names:

NoCoding1 Plus Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
CGA	II	21 CFR 862.1345 - Glucose test system	Chemistry (75)
NBW	II	21 CFR 862.1345 - Glucose test system	Chemistry (75)
JJX	I, reserved	21 CFR 862.1660 – Quality Control Material (assayed and unassayed)	Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

   The NoCoding1 Plus Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip. The NoCoding1 Plus Blood Glucose Monitoring System is intended for self-testing outside the body (for in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The system is intended to be used by a single person and should not be shared. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.

   The NoCoding1 Blood Glucose Test Strips are for use with the NoCoding1 Plus Blood Glucose Meters to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.

   The NoCoding1 Glucose Control Solutions are for use with the NoCoding1 Plus Blood Glucose Meters and NoCoding1 Blood Glucose Test Strips to check that the meter and the test strips are working together properly and that the test is performing correctly.

3. Special conditions for use statement(s):
   - An abnormally high or low red blood cell count (hematocrit level over 65% or below 15%) may produce inaccurate results.
   - Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hypoglycemic hyperosmolar state, with or without ketosis.
   - Dehydration (excessive water loss) may cause false low results. If you believe you are suffering from dehydration, consult your healthcare professional immediately.
   - Altitudes of higher than 10,000 ft. (3,048 m) above sea level may have an effect on the performance of the test strip.
   - The single-patient use system is for single-patient use only and should not be shared.
   - Not for neonatal use.
   - Do not use for diagnosis of or screening for diabetes mellitus.
   - Not for use on critically ill patients.
   - For *in vitro* diagnostic use only.
   - For over the counter use.

4. Special instrument requirements:

   NoCoding1 Plus Blood Glucose Meter

I. Device Description:

The NoCoding1 Plus Blood Glucose Monitoring System (BGMS) consists of the NoCoding1 Plus blood glucose meter, the NoCoding1 test strips, and NoCoding1 Control solutions with two different glucose concentrations ("Control A" and "Control B").

J. Substantial Equivalence Information:

1. Predicate device name(s):

   CareSens N Blood Glucose Monitoring System

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

   k083468

3. Comparison with predicate:

Similarities		
Item	Candidate Device NoCoding1 Plus Blood Glucose Monitoring System	Predicate Device CareSens N Blood Glucose Monitoring System (k083468)
Indications for use	Intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Enzyme	Glucose Oxidase	Same
Measurement principle	Amperometric	Same
Calibration	Plasma-equivalent	Same
Sample volume	0.5 μL	Same
Test time	5 seconds	Same
Test range	20 ~ 600 mg/dL	Same
Coding system	No coding required (Automatic code identification)	Same

Differences		
Item	Candidate Device NoCoding1 Plus Blood Glucose Monitoring System	Predicate Device CareSens N Blood Glucose Monitoring System (k083468)
Test result average range	1, 7,14, 30 and 90 days (Pre-meal, Post-meal, Fasting and Total)	14 days (Pre-meal, Post-meal, and Total)
Sample Type	Fresh capillary whole blood from the fingertip	Fresh capillary whole blood from the fingertip, forearm, palm, thigh and calf.
Hematocrit range	15~65%	20~60%
Memory capacity	Up to 1,000 test results	Up to 250 test results

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

CLSI EP07-A2, "Interference Testing in Clinical Chemistry"; Approved Guideline

CLSI EP06-P, A "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach"

L. Test Principle:

The NoCoding1 Plus Blood Glucose Monitoring System quantitatively measures blood glucose levels using an amperometric method. A blood sample is drawn into the test strip by capillary action, and reacts with reagents (glucose oxidase) on the test strip. This reaction produces an electrical current which is proportional to the concentration of glucose in the samples. The electrical current is measured by the meter and is displayed to the user as a corresponding blood glucose concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor performed repeatability precision studies (within-run precision) using pooled venous whole blood samples spiked with glucose to five glucose concentration ranges (30-50 mg/dL, 51-80 mg/dL, 100-150 mg/dL, 151-250 mg/dL, 251-400 mg/dL). Each glucose sample was measured in replicates of 10 using 3 test

strip lots and 10 meters for a total of 300 tests for each glucose level. Results are summarized below:

Glucose Level, (mg/dL)	Strip Lot	n	Average Glucose (mg/dL)	SD (mg/dL)	CV (%)
Level 1	1	100	41.6	2.3	5.2
	2	100	44.1	1.7	3.9
	3	100	43.8	1.7	3.8
	Combined			1.9	4.3
Level 2	1	100	69.6	2.0	2.8
	2	100	70.2	2.3	3.3
	3	100	72.2	1.9	2.8
	Combined			2.1	2.9
Level 3	1	100	134.2	3.8	2.8
	2	100	135.5	3.6	2.6
	3	100	135.4	3.9	2.9
	Combined			3.8	2.8
Level 4	1	100	202.2	4.1	2.0
	2	100	203.2	6.1	3.0
	3	100	205.0	2.7	2.7
	Combined			5.2	2.6
Level 5	1	100	344.0	7.3	2.1
	2	100	336.3	11.4	3.4
	3	100	348.8	13.3	3.8
	Combined			11.0	3.2

Intermediate (between run) precision was evaluated using 3 levels of glucose control solutions (Level 1: 30 to 50, Level 2: 96 to 144 and Level 3: 280 to 420 mg/dL) using 3 meters each and 3 test strip lots over 10 days, for a total 300 tests per glucose level. Results are summarized below:

Glucose Level, (mg/dL)	Strip Lot	n	Average Glucose (mg/dL)	SD (mg/dL)	CV (%)
Level 1	1	100	36.1	1.4	3.7
	2	100	36.3	1.3	3.5
	3	100	34.6	1.5	4.2
	Combined			1.4	3.8
Level 2	1	100	114	3.4	3.0
	2	100	115	3.1	2.7
	3	100	112	3.8	3.4
	Combined			3.4	3.0
Level 3	1	100	341	7.8	2.3
	2	100	345	7.1	2.1
	3	100	338	9.6	2.8
	Combined			8.2	2.4

b. Linearity/assay reportable range:

Linearity testing was performed using venous whole blood spiked with glucose. A total of 9 concentrations ranging from 13 mg/dL to 614 mg/dL were tested using 3 lots of test strips. Results from the regression analysis are as follows:

Lot	Slope	y-intercept	R^2
1	0.9794	-1.3703	0.9996
2	0.9815	-0.5658	0.9996
3	0.9916	-2.2810	0.9994
Combined	0.9814	-1.3847	0.9995

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

The NoCoding1 Plus Blood Glucose Meter displays results between 20-600 mg/dL. The message 'HI' appears when results are greater than 600 mg/dL and the message 'Lo' appears when a test result is less than 20 mg/dL. The 'HI/Lo' error message feature was validated during the software validation of the device to demonstrate that the feature functions as intended.

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

Traceability:
The NoCoding1 Plus Blood Glucose Monitoring System is traceable to a certified

reference material (NISTa SRM 917b).

Test Strip Stability:

Test Strip stability has been evaluated through accelerated and real-time open vial and closed vial studies. Protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims shelf life stability and open vial stability of 24 months from manufacture when stored at 34- 86°F (1-30˚C) and 20-80% Relative Humidity. The labeling states not to freeze test strips.

Control Solution Value Assignment and Stability:

The NoCoding 1 Control Solutions were previously cleared as CareSens Control Solutions under k080923 where the value assignment protocol, the stability protocols and acceptance criteria were reviewed and found to be acceptable. They have been repackaged and renamed in this submission. The stability studies support a closed-vial shelf life of 24 months when stored at 46-86°F (8-30°C) and an open-vial shelf life of 90 days when stored at 46-86°F (8-30°C).

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on linearity studies (see section M.1.b above).

e. Analytical specificity:

Interference studies were performed by spiking endogenous and exogenous substances into venous whole blood. Each potential interferent was tested at 2 glucose levels (80 and 300 mg/dL) using 3 test strip lots and 10 replicates per lot per interferent. Results of test samples measured on the NoCoding1 Plus Blood Glucose Meter System were compared to the mean of the control sample measured by a laboratory reference method (YSI) and the bias calculated. Significant interference is defined by the sponsor as a bias within ± 10% compared to a control sample. Results are presented in the table below:

Substance	Highest Concentration tested with no observed significant interference
Acetaminophen	20 mg/dL
Ascorbic acid	3 mg/dL
Bilirubin unconjugated	20 mg/dL
Cholesterol	500 mg/dL

Substance	Highest Concentration tested with no observed significant interference
Creatinine	30 mg/dL
Dopamine	13 mg/dL
EDTA	180 mg/dL
Galactose	60 mg/dL
Gentisic Acid	50 mg/dL
Glutathione	17 mg/dL
Hemoglobin	500 mg/dL
Heparin	8000 U/dL
Ibuprofen	40 mg/dL
Icodextrin	2 mg/dL
L-Dopa (Levo-Dopa)	5 mg/dL
Maltose	1000 mg/dL
M-Dopa (Methyl-Dopa)	1.50 mg/dL
Salicylic Acid	60 mg/dL
Tolazamide	100 mg/dL
Tolbutamine	100 mg/dL
Triglycerides	3000 mg/dL
Uric Acid	20 mg/dL
Xylose	300 mg/dL

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

To assess the performance of the NoCoding1 Plus Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a study at three clinical sites with a total of 371 participants (121, 123 and 127 lay users at each site respectively)

who collected and tested samples from their own fingertip. A total of fifteen lots (each assigned with a different calibration code) of NoCoding1 test strips and ten NoCoding1 Plus Blood Glucose meters were used. Results were analyzed by comparing the capillary whole blood glucose results obtained by the lay users with the NoCoding1 Plus Blood Glucose Monitoring System against results obtained with a laboratory reference method (YSI). The glucose concentrations in the samples ranged from 48 to 553 mg/dL. The results are shown below:

For glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
25/41 (61.0%)	40/41 (97.6%)	41/41 (100.0%)

For glucose concentrations > 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
231/330 (70.0%)	317/330 (96.1%)	330/330 (100%)	330/330 (100%)

Linear regression analysis

Slope	Intercept	R^2	N	Glucose Concentration range (new meter) (mg/dL)
1.0223	-1.3686	0.9934	371	48 to 553

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):*

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

The range of a normal fasting blood glucose level for non-diabetic adults is between 70-99 mg/dL (3.9-5.5 mmol/L).
Two (2) hours after a meal, the range of a normal blood glucose level for non-diabetic adults is less than 140 mg/dL (7.8 mmol/L).

American Diabetes Association. "Standards of Medical Care in Diabetes - 2015." Diabetes Care. January 2015; 39(1):S15, S100.

N. Instrument Name:

NoCoding1 Plus 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 _____ 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. As the blood sample was collected from the fingertip, the user directly applies the blood sample to the test strip.

4. Specimen Sampling and Handling:

   NoCoding1 Plus Blood Glucose System is used for measuring fresh capillary whole blood samples from the fingertip. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   There is no calibration required by the user for the NoCoding1 Plus blood glucose meters. The meters are automatically coded.

6. Quality Control:

   Two levels of glucose control solutions are available with this system, but are sold separately. Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the control solutions vial label. The user is cautioned not to use the meter and to contact customer support 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

   The effect of different hematocrit levels on the performance of the NoCoding1 Plus Blood Glucose Monitoring System was evaluated using venous whole blood samples with seven hematocrit levels of 15, 20, 30, 42, 50, 60 and 65% spiked with glucose to achieve three (3) concentrations at 30-50, 96-144, and 280-420 mg/dL. Each sample was then tested using 30 NoCoding1 Plus meters and three (3) lots of test strips. The values obtained on the meter were compared with those obtained using the YSI 2300 analyzer. The % biases relative to YSI demonstrated acceptable performance across the claimed hematocrit range of 15-65%.

2. Altitude Testing

   An altitude study was conducted inside an altitude test chamber that has capabilities of controlling both pressure and oxygen variables. Various altitudes (0 feet, 5,000 feet and 10,000 feet) were simulated for testing. Venous blood samples with three glucose concentrations intervals (60 to 80, 150 to 250, and 350 to 500 mg/dL) were tested using three lots of NoCoding 1 Plus blood glucose strips and fifteen NoCoding 1 Plus meters. The results obtained using the NoCoding1 Plus Blood Glucose monitoring system were compared to results obtained using the YSI analyzer. The results demonstrate acceptable bias to YSI to support the claims in the labeling that altitudes up to 10,000 feet (3048

meters) have no significant effect on blood glucose measurements on the NoCoding1 Plus Blood Glucose Monitoring System.

3. Sample volume study:

The sponsor performed a study to support the claimed minimum sample volume for the NoCoding1 Plus system. Blood samples with three levels of glucose (<75, 80-120, and >250 mg/dL) were tested at three sample volumes (0.4, 0.5, and 0.6µL) using 3 test strip lots and 3 meters. The values obtained using the NoCoding1 Plus system were compared to values obtained using the YSI analyzer. Results support the claimed minimum sample volume of 0.5 µL.

4. Temperature and Humidity

The sponsor performed operating conditions studies using venous blood samples at three glucose concentrations (60 to 80, 96 to 144, and 280 to 420 mg/dL) to evaluate temperatures from 6°C to 44°C and relative humidity (RH) from 10 % to 90 % RH. Nine temperature and humidity combinations were tested including low temperature/low humidity, low temperature/medium humidity, low temperature/high humidity, average temperature/low humidity, average temperature/medium humidity, average temperature/high humidity, high temperature/low humidity, high temperature/medium humidity, and high temperature/high humidity. Individual glucose measurements using the NoCoding1 Plus Blood Glucose Monitoring System were compared to the reference method (YSI) and percent bias were calculated. Results demonstrated that glucose measurements on the NoCoding1 Plus Blood Glucose Monitoring System were not significantly affected by the tested conditions. The results support the claims in the labeling that the system can be used in temperature conditions of 42.8-111.2˚F (6°C to 44°C) and relative humidity between 10 to 90%.

4. Infection control studies:

The NoCoding1 Plus Blood Glucose Monitoring System is intended for single patient home use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of viral hepatitis B virus (HBV) with the chosen disinfectant, Clorox Germicidal Wipes (EPA Reg. No: 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 10,950 cleaning and disinfection cycles designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

5. EMC Testing:

The sponsor provided appropriate documentation certifying that electromagnetic (EMC) testing was performed and the NoCoding1 Plus Blood Glucose Monitoring System were found to be compliant.

6. Usability Study:

   A usability study was performed and a questionnaire designed to evaluate the ease of use of the device and the clarity of the English language labeling was completed by the subjects. The test subjects varied in gender, age and highest level of education. The responses to the Instructions for Use Questionnaire met the acceptance criteria, with lay users demonstrating acceptable levels of comprehension of the labeling. The readability assessment using a Flesch-Kincaid analysis for the NoCoding1 Plus User Manual, the NoCoding1 Test Strip Insert and NoCoding1 Control Solution was found to be 8.0.

7. 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 submission was received 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.