

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

A. 510(k) Number:

k180866

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose from the fingertip

D. Type of Test:

Quantitative, amperometric detection, Glucose Oxidase

E. Applicant:

i-SENS, Inc.

F. Proprietary and Established Names:

CareSens S Fit Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1345, Glucose Test System

2. Classification:

Class II

3. Product code:

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

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The CareSens S Fit Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The CareSens S Fit Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro) 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 CareSens S Blood Glucose Test Strips are for use with the CareSens S Fit Blood Glucose Meters to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.

3. Special conditions for use statement(s):

- For in vitro diagnostic use only.
- For over the counter use.
- For single-patient use only and should not be shared.
- 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 inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- An abnormally high or low red blood cell count (hematocrit level over 60% or below 20%) may produce inaccurate results.
- Altitudes of higher than 10,000 ft. (3,048 m) above sea level may influence the performance of the test strip.
- Not for neonatal use.
- Do not use for diagnosis of or screening for diabetes mellitus.
- Not for use on critically ill patients.
- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

4. Special instrument requirements:

CareSens S Fit Meter

I. Device Description:

The CareSens S Fit Blood Glucose Monitoring System consists of the CareSens S Fit Meter, CareSens S Blood Glucose Test Strips (sold separately), CareSens S Glucose Control Solutions (Level 1 and Level 2; sold separately), lancing device and lancets for single patient use, owner's booklet and quick reference guide.

J. Substantial Equivalence Information:

1. Predicate device name(s):

CareSens N Premier Blood Glucose Monitoring System

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

k170614

3. Comparison with predicate:

Similarities		
Item	CareSens S Fit BGMS (Candidate Device)	Predicate (k170614)
Intended Use	Intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips by people with diabetes at home as an aid to monitor the effectiveness of diabetes control	Same
Test principle	Amperometric	Same
Enzyme	Glucose Oxidase	Same
Sample type	Fresh capillary whole blood from fingertips	Same
Coding system	None require (Automatic code identification)	Same
Operating humidity	10-90% RH	Same
Data communication	USB	Same

Differences		
Item	CareSens S Fit BGMS (Candidate Device)	Predicate (k170614)
Test range	40-600 mg/dL	20-600 mg/dL
Operating temperature	50-104° F	42.8-111.2° F
Power source	One 3.0V lithium battery (CR2032)	Two 3.0V lithium batteries (CR2032)
Hematocrit range	20-60%	15-65%

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

CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline

CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A statistical Approach; Approved Guideline

CLSI EP07-A2, 2005, Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition

IEC 61010-1 Edition 3.0 2010-06, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General Requirements [including: Corrigendum 1 (2011)]

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 Compatibility - Requirements and Tests

IEC 62304:2006, Medical Device Software - Software Life Cycle Processes

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter-Use, Guidance for Industry and Food and Drug Administration Staff. October 11, 2016.

L. Test Principle:

The glucose measurement of the CareSens S Fit system is based on an electrochemical biosensor technology. The glucose level in the whole blood sample is oxidized by the enzyme glucose oxidase and the resulting electrical current generated from the enzymatic reaction is measured and converted to a glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample. The resulting glucose result is displayed by the meter for the user.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Repeatability (within-day) precision studies were conducted by the sponsor using venous whole blood samples adjusted to five glucose concentration levels (30-50, 51-110, 111-150, 151-250, and 251-400 mg/dL). Each glucose concentration level was analyzed in replicates of 10, with 3 test strip lots and 10 meters, for a total of 100 replicates per glucose level per test strip lot (for a total of 300 tests per each glucose level for 10 meters). Results are summarized below:

Blood Glucose Level (mg/dL)	Strip Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1 (30-50)	1	100	42.5	1.9	4.5
	2	100	43.3	1.4	3.2
	3	100	45.3	1.9	4.2
	Combined	100	43.7	1.8	4.1
Level 2 (51-110)	1	100	59.3	2.9	4.9
	2	100	63.4	2.0	3.2
	3	100	64.3	2.5	3.9
	Combined	100	62.3	2.5	4.0
Level 3 (111-150)	1	100	122.1	4.1	3.4
	2	100	128.2	2.9	2.3
	3	100	127.9	3.6	2.8
	Combined	100	126.1	3.6	2.9
Level 4 (151-250)	1	100	187.7	7.2	3.8
	2	100	196.5	4.5	2.3
	3	100	194.8	5.9	3.0
	Combined	100	193.0	6.0	3.1
Level 5 (251-400)	1	100	295.4	10.5	3.6
	2	100	310.0	7.3	2.3
	3	100	304.8	9.1	3.0
	Combined	100	303.4	9.0	3.0

Intermediate (day-to-day) precision was evaluated using five levels of glucose control solutions with concentration ranges of 30-50, 111-150, and 251-400 mg/dL. Each sample was measured once per day using ten meters and three test strip lots, over 10 days for a total of 300 tests per glucose level. Results are summarized below:

Control Solution Level (mg/dL)	Strip Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1 (30-50)	1	100	44.2	0.7	1.6
	2	100	45.4	0.9	2.0
	3	100	44.5	0.9	2.0
	Combined	300	44.7	0.8	1.8
Level 2 (51-110)	1	100	72.6	1.5	2.1
	2	100	75.0	1.6	2.1
	3	100	73.2	1.6	2.2

Control Solution Level (mg/dL)	Strip Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
	Combined	300	73.6	1.5	2.0
Level 3 (111-150)	1	100	119.4	3.4	2.8
	2	100	124.3	3.2	2.6
	3	100	121.4	3.5	2.9
	Combined	300	121.7	3.4	2.8
Level 4 (151-250)	1	100	187.6	6.0	3.2
	2	100	195.7	6.1	3.1
	3	100	191.5	6.4	3.3
	Combined	300	191.6	6.2	3.2
Level 5 (251-400)	1	100	307.1	12.4	4.0
	2	100	319.4	12.7	4.0
	3	100	316.3	12.9	4.1
	Combined	300	314.2	12.7	4.0

b. *Linearity/assay reportable range:*

Linearity testing was performed using eleven venous whole blood samples with the following glucose concentrations (as measured by the comparator method YSI 2300): 37.4 , 46.1, 109, 181, 245, 316, 378, 448, 519, 584, and 649 mg/dL (as established using a laboratory comparator method YSI 2300). Each level was measured in replicates of 15 using three test strip lots and the values from the CareSens S Fit meter were compared with those obtained from the YSI 2300. The evaluation yielded the following regression equations:

Strip Lot	Slope	Y-Intercept	R ²
1	0.953	-0.432	1
2	0.954	-0.747	0.999
3	0.948	1.817	1.000
Combined	0.952	0.219	1.000

The results of the study support the sponsor’s claimed glucose measurement range of 40 - 600 mg/dL. If a sample result is less than 40 mg/dL glucose, the result is flagged by the meter as “Lo”. If a sample result exceeds 600 mg/dL glucose, the result is flagged by the meter as “Hi”. The “Lo” and “Hi” functions were validated by the sponsor and were demonstrated to function as intended.

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

Traceability

The CareSens S Fit Blood Glucose Monitoring System is traceable to NIST-965B glucose reference material. The method comparison study (section M.3.c below) was performed with the candidate device and the YSI 2300 analyzer as the comparator method.

Test Strip Stability

Stability of CareSens S Blood Glucose Test Strips were assessed using real time and accelerated testing. Protocols and acceptance criteria for were reviewed and found to be acceptable. The sponsor claims shelf life stability of 2.2 years and open-vial stability of 5 months when stored at the recommended storage conditions of 34°F-86°F (1-30°C) and 20-80% relative humidity (RH).

d. Detection limit:

The reportable range, verified by the linearity study (Section M.1.b.) is 40-600 mg/dL.

e. Analytical specificity:

Interference studies were performed by spiking endogenous and exogenous substances into venous whole blood at 3 glucose levels (50-70, 110-130, and 225-270 mg/dL). The CareSens S Fit meter results obtained from samples containing potential interfering substances were compared to meter results obtained with samples containing no added potential interferent. Samples were tested at each glucose level using 3 test strip lots in replicates of 10. The highest concentration of each substance tested with no significant interference (as defined by the sponsor as bias ≤ 10 mg/dL for glucose < 75 mg/dL or $\leq 10\%$ or glucose ≥ 75 mg/dL) is summarized in the following table:

Substance	Highest tested concentration with no significant interference (mg/dL except where noted)
Acetaminophen	20
Ascorbic Acid	3
Conjugated Bilirubin	50
Unconjugated Bilirubin	40
Cholesterol	500
Creatinine	10
Dopamine	20
EDTA	200
Galactose	15
Gentisic Acid	100
Glutathione (Reduced)	92
Hemoglobin	17.7 g/dL
Heparin	500 IU/dL
Ibuprofen	50
Icodextrin	1094.4
L-Dopa	0.5
Maltose	2500
Methyldopa	1000
Salicylic Acid	60

Sodium	414
Tolbutamide	100
Tolazamide	40
Triglycerides	1500
Uric Acid	24
Xylose	200
Mannitol	0.09
Sorbitol	0.09
Xylitol	0.09
Lactitol	0.09
Isomalt	0.09
Maltitol	0.09
Dulcitol	0.09
Ketone	6 mmol/L
Arahitol	0.09
Maltotriose	0.09
Inositol	0.09
Adoritol	0.09
Lactose	0.09
Stachyose Hydrate	0.09
Trehalose Dehydrate	0.09
Raffinose Pentahydrate	0.09
Melezitose	0.09
Maltodextrin	0.09
Threitol	0.09
2-Deoxy-D-Glucose	0.09
Meso-Erythritol	0.09
D-Mannose	0.09
Maltotriose	0.09
Arabinose	0.09
Fructose	0.09
Sucrose	0.09
Glycerol	47

Based on these results, the sponsor has added the following statement to their labeling: If you are taking Vitamin C (ascorbic acid) at doses higher than recommended (resulting in blood concentrations greater than 3 mg/dL), it may interfere with your glucose meter and cause you to get inaccurate results with this system.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

See the lay-user study below (section M.3.d) for demonstration of system accuracy in the hands of the intended user.

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):*

Lay-User Study

To assess the performance of the CareSens S Fit Blood Glucose Monitoring System in the hands of the intended user, the sponsor performed a lay-user evaluation study with 376 lay user participants who collected and tested samples from their own fingertips using only the device labeling as instructions. Results were analyzed by comparing the blood glucose results obtained using the CareSens S Fit System to results obtained with a laboratory comparator method (YSI 2300). Glucose concentrations in study ranged from 55.6 to 441.5 mg/dL as measured by YSI 2300. The results relative to YSI values are summarized below:

Within ±5%	Within ±10%	Within ±15%	Within ±20%
235/376 (62.5%)	343/376 (91.2%)	369/376 (98.1%)	376/376 (100%)

Linear Regression Equation: $y = 0.9972x + 1.2038$, $r^2 = 0.9913$

For glucose concentrations ≥ 75 mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
226/359 (63.0%)	330/359 (91.9%)	353/359 (98.3%)	359/359 (100.0%)

Accuracy of CareSens S Fit BGMS vs. YSI2300 at Extreme Glucose Values

To assess the performance of the system with extreme glucose concentrations (< 80 mg/dL and > 250 mg/dL) the sponsor altered capillary blood samples, by spiking or allowing samples to glycolyze, to achieve glucose concentrations below 80 mg/dL (42.6 to 77.1 mg/dL, as measured by YSI 2300) and above 250 mg/dL (253.3 to 567.5 mg/dL, as measured by YSI 2300). Results were analyzed by comparing the blood glucose results obtained on the CareSens S Fit BGMS against YSI 2300 results. The data is summarized below:

Glucose < 80 mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
31/50 (62%)	43/50 (86%)	50/5 (100%)	50/50 (100%)

Glucose > 250 mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
40/50 (80%)	50/50 (100%)	50/50 (100%)	50/50 (100%)

Readability/Usability Study:

A readability assessment indicated a Flesch-Kincaid Score of 8 and lower for all instructional materials included with this device.

Upon completion of lay user measurements, study participants were administered a questionnaire to evaluate the ease in which instructions for use were readily understood. The study demonstrated that users of the device were able to understand and follow the instructions provided in the labeling to perform tasks involved in blood glucose testing.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Normal blood glucose levels for an adult without diabetes are below 100 mg/dL before meals and fasting* and are less than 140 mg/dL two hours after meals.

*Fasting is defined as no caloric intake for at least eight hours.

Reference: American Diabetes Association (Standards of Medical Care in Diabetes – 2018. Diabetes Care, January 2018, vol. 41, Supplement 1, S13-S27)

N. Instrument Name:

CareSens S Fit 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. 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 user calibration is required.

6. Quality Control:

CareSens S Control Solutions are for use with the CareSens S Fit Blood Glucose Meter and CareSens S Fit Blood Glucose Test Strips to check that the meter and the test strips are working together properly and that the test is performing correctly. Two control solution levels (1 and 2) are available. Control solutions must be purchased separately from the system. The control solution readings are not included in the average of the patient results when the measurements are performed in the “Control Solution Test Mode”. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

P. Other Supportive Instrument Performance Characteristics Data Not Covered in the “Performance Characteristics” Section above:

1. Hematocrit Study:

The effect of different hematocrit levels on the performance of the CareSens S Fit Blood Glucose Monitoring System was evaluated using venous whole blood samples with 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, and 60% hematocrit at glucose levels of 30-5, 51-110, 111-150, 151-250, and 251-400 mg/dL. Measurements were taken with 10 glucose meters and 3 test strip lots and values compared with those obtained from the comparator method, YSI-2300. The study results support the claimed hematocrit range of 20-60%.

2. Operating Conditions Study:

The sponsor performed operating condition studies using venous whole blood samples with three glucose levels (40-65, 100-150, 200-300 mg/dL) to evaluate temperatures ranging from 50°F - 104°F (10-40°C) and relative humidity from 10% to 90%. Meter results were compared to the YSI 2300 comparator method. Four temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity. The results support the claims in the labeling that the system can be used in conditions of 50°F - 104°F (10-40°C) with relative humidity of 10 to 90%.

3. Altitude Tests:

Three sets of venous blood samples were adjusted to 3 blood glucose levels: 50-65, 100-120, and 200-250 mg/dL. Each sample was measured using YSI 2300 as well as 10 CareSens S Fit BGMS meters using 3 test strip lots under simulated altitude conditions in an adjustable barometric pressure chamber. Three simulated conditions were tested: 0 m (Sea Level, 760 mm Hg), 1524 m (5,000 ft, 632 mm Hg), 3048 m (10,000 ft, 522 mm Hg). The results support the labeling claims that altitudes up to 10,000 feet have no significant effect on performance of the CareSens S Fit System.

4. Short Sample Detection

Three venous blood samples were prepared at three glucose range intervals (50-65 mg/dL, 100-120 mg/dL, and 200-250 mg/dL). Meter results were compared against duplicate YSI 2300 measurements. Results support the claimed minimum sample volume of 0.5 μ L. The sponsor provided validation studies demonstrating that with blood volumes below 0.5 μ L, the insufficient sample volume error message functioned as intended.

5. Sample Perturbation Study

To evaluate system performance when sample is perturbed during testing, test strips were disturbed by bending, flicking, and flicking the meter during measurement. Venous blood samples were prepared at three glucose range intervals (63.3 mg/dL, 118.3 mg/dL, and 241.5 mg/dL per YSI2300). Meter results were compared against YSI 2300 measurements. Results demonstrated that meter measurement was insensitive to sample perturbation of the test strip or meter during sample measurement.

6. Intermittent Sampling

To evaluate system performance during intermittent sampling, venous whole blood samples were prepared at three glucose range intervals (50-65 mg/dL, 100-120 mg/dL, and 200-250 mg/dL). Samples were applied to the test strip intermittently (i.e., within 1 second or over a period a several seconds). The results demonstrated that, when the full sample was applied within one second, a valid test results was generated, whereas intermittent sampling beyond one second generated an error message on the meter. Thus, the system was validated to be robust to intermittent sampling, and the error code functioned as intended to prevent erroneous results.

7. Testing with Used Test Strips

A study was performed to demonstrate that the system is capable of detecting when a test strip had previously been measured or if sample was applied to a test strip prior to insertion in the meter. The meter correctly displayed the "Er 1" message whenever a used test strip was inserted.

8. Device Stress Testing:

To assess insensitivity of the CareSens S Fit Blood Glucose meter to extreme physical stresses that may be encountered in the intended use environment by performing various tests such as drop testing, vibration testing, temperature and humidity exposure limit testing Results demonstrated that the meter is insensitive to certain stresses that may be encountered during use.

9. Cleaning and Disinfection Validation:

The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the external materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Healthcare Bleach Germicidal Wipes (EPA Registration #67619-12). A robustness study was also conducted by the sponsor demonstrating that there was no change in performance or in the external materials of the meter after 260

cleaning and disinfection cycles using the Clorox Healthcare Bleach Germicidal Wipes. The robustness studies were designed to simulate 5 years of single-patient device use. Each cycle consisted of 3 horizontal and 3 vertical cleaning passes across the front, sides, and back of the meter. After one minute, the entire meter is wiped with a dry cloth and the process is repeated using a second disinfectant wipe and a second dry cloth. One pass was defined as a back and forth motion. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

R. Conclusion:

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