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

A. 510(k) Number:
k130696

B. Purpose for Submission:
To add two additional names to their cleared system: CareSens N LINK Blood Glucose Monitoring System and, CareSens N LINK Multi Blood Glucose Monitoring System. To add validated cleaning and disinfection instructions for multiple-patient use to the labeling, change the shape of the meters' housing, change the software (test result average range and memory functions), and the battery type as compared to the previously cleared CareSens N Blood Glucose Monitoring System (k083468).

C. Measurand:
Capillary whole blood glucose

D. Type of Test:
Quantitative Amperometric assay (Glucose oxidase)

E. Applicant:
i-Sens, Inc.

F. Proprietary and Established Names:
CareSens N LINK Blood Glucose Monitoring System
CareSens N LINK Multi 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
   CGA, Glucose Oxidase, Glucose

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indications for use below.

2. Indication(s) for use:

   The CareSens N LINK Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites such as the forearm, palm, thigh, and calf. Alternative site testing should be used only during steady-state blood glucose conditions. The 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 N Single Blood Glucose Test Strips are for use with the CareSens N LINK Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites.

   The CareSens N LINK Multi Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites such as the forearm, palm, thigh, and calf. Alternative site testing should be used only during steady-state blood glucose conditions. The system is intended for use outside the body (in vitro) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with auto-disabling, single use lancing device. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.

   The CareSens N Multi Blood Glucose Test Strips are for use with the CareSens N LINK Multi Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites.

3. Special conditions for use statement(s):
   - For over-the-counter use
   - Not for neonatal use
   - Not for screening or diagnosis of diabetes mellitus
   - Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients
   - Alternative site testing (AST) testing should only be done during steady-state times (when glucose is not changing rapidly).
   - AST should not be used to calibrate continuous glucose monitors (CGMs).
   - AST should not be used for insulin dose calculations.

- Use only auto-disabling, single-use lancing device with multiple-patient use system.
- Lancing devices used in a single patient use system should not be shared.

4. Special instrument requirements:
   CareSens N LINK Blood Glucose Monitoring System
   CareSens N LINK Multi Blood Glucose Monitoring System

I. Device Description:

The CareSens N LINK Blood Glucose Monitoring System or the CareSens N LINK Multi Blood Glucose Monitoring System each consists of a CareSens N LINK Blood Glucose meter, CareSens N Single Blood Glucose Test Strips (sold separately), and CareSens Control Solutions (sold separately), a user manual, logbook, carrying case, and two batteries). The CareSens N LINK Blood Glucose Monitoring System has a lancing device, 10 lancets, and a quick reference guide.

Each test strip contains the following reagent compositions: glucose oxidase (20.09 % sourced from *Aspergillus niger.*); Hexammineruthenium (III) Chloride (45.7 μg), and other non-reactive ingredients (1.6 μg).

CarSens controls were previously cleared (k083468). Each box of control solutions contains one vial of each aqueous control solution, each: Control A, and Control B.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   CarSens N Blood Glucose Monitoring System

2. Predicate K number(s):

   k083468

3. Comparison with predicate:

Similarities and Differences of the Blood Glucose System		
Item	CareSens N Blood Glucose Monitoring System, (k083468)	Candidate Device CareSens N LINK Blood Glucose Monitoring System and CareSens N LINK Multi Blood Glucose Monitoring System
Similarities		
Intended Use/Indications for Use	It is 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
Detection method	Amperometry	Same
Enzyme	Glucose Oxidase	Same
Calibration Coding	No coding	Same
Test range	20-600 mg/dL	Same
Hematocrit range	20-60%	Same
Sample type	Capillary whole blood	Same
Sample sites	Fingertip, Palm, forearm, calf and thigh.	Same
Sample volume	0.5 µL	Same
Sample test time	5 seconds	Same
Memory Capacity	250 Tests	500 Tests
Differences		
Test Average range	14 days	1, 7, 14, 30, and 90 days
Battery Type	Two 3.0 V CR2032 lithium batteries	Two 1.5 V AAA alkaline batteries
Test strip ejector	No	Yes

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

- ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- EC 61326-2-6: Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostics (IVD) medical equipment
- IEC 61010-2-101: Safety requirements for electrical euiptment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equiptment
- PCC Part 15C rule: Radio Frequency Devices, Subpart C – Intentional Radiators

L. Test Principle:

The glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip's electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, and the current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):

The meter and test strips for the CareSens N LINK and CareSens N LINK Multi Blood Glucose Monitoring Systems are the same components. The two Systems only differ in name and intended use (single- versus multiple-patient use). Therefore, one set of data are presented for both test systems. This submission, changes the shape of the meter's housing, makes changes to software (test result average range and memory), and changes the battery type for previously cleared CareSens N Glucose meters.

1. Analytical performance:

   a. Precision/Reproducibility:

   Precision/Reproducibility were previously established in k083468:

   b. Linearity/assay reportable range:

   Linearity was previously established in k083468:

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

   Traceability:

   As established in k083468

   Test Strip Stability:

   As established in k083468
   When stored unopened at the recommended storage temperature is 34° F to 86°F (1-30°C) and between 10-90% relative humidity.

   Control Solution Value Assignment and Stability:

   As established in k083468
   When stored unopened at the recommended storage temperature is 34° F to 86°F (1-30°C).

   d. Detection limit:

See linearity study in Section M1b above.

e. Analytical specificity:

As established in k080923

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:
System Accuracy for all claimed sampling sites was previously established in k080923.

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 was previously established in k080923

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. Two hours after a meal, the range of a normal blood glucose level for non-diabetic adults is between 100 – 139 mg/dL. Fasting is defined as no caloric intake for at least eight hours.

Reference: American Diabetes Association. "Standards of Medical Care in Diabetes – 20-12." *Diabetes Care*. January 2012; 35(1):S11-S63.

N. Instrument Name:
CareSens N LINK Meter
CareSens N LINK Multi Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:
   Each test strip is single use and requires a sample volume of 0.5 μL.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes __X__ or No _____.

   As established in K100937.

   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 glucose test is intended to be used with capillary whole blood from the finger and forearm, palm, thigh, and calf. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:
   The meter is autocoded, therefore no coding is required by the user. The coding circuit printed on the test strip is consistent with the code in the meter and the meter detects the code of the strip.

6. Quality Control:
   Control A, and Control B are available for use with this system (sold separately). The meter has a control solution test mode. The control solution readings are not included in the average of the patient results when the measurements are performed in the control solution mode. An acceptable range for each control level is printed on the test strip vial label. Recommendations on when to test the control materials are provided in the labeling and what the user should do 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:
As established in k080923

2) Altitude study:
As established in k080923

3) Sample volume study:
As established in k080923

4) Temperature and humidity studies:
As established in k080923

5) Infection Control Studies: The CareSens N LINK Blood Glucose Monitoring System is intended for single-patient use only. Clorox Germicidal Wipes with EPA registration number 67619-12 were validated demonstrating complete inactivation of live virus for use with the meter and lancing device. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter after 260 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 5 years of meter use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

   CareSens N LINK Multi Blood Glucose Monitoring System is intended for multiple-patient use in a health care setting. Clorox Germicidal Wipes with EPA registration number 67619-12 were validated demonstrating complete inactivation of live virus for use with the meter. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter after 10,950 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 3 years of meter use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

1) EMC testing was evaluated and certified by EMC Compliance Ltd (Korea), and Verification of Compliance certificates provided.

2) Flesch-Kincaid readability assessment was conducted and the results demonstrated that the User Manual, test strip package insert and control solution package insert were written at the 8^{th} grade level.

3) Customer support is available Monday through Friday 9:00 am to 9:00 pm EST by calling 1-800-429-5001.

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.