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

A. 510(k) Number:
k100937

B. Purpose for Submission:
New 510(k) for diabetes data management software accessory to cleared glucose meters - k080923 (CareSens II) and k083468 (CareSens N)

C. Measurand:
Whole blood glucose

D. Type of Test:
Data management system for i-SENS glucose meters with PC care USB cable

E. Applicant:
I-SENS, Inc.

F. Proprietary and Established Names:
PC care Blood Glucose Data Management Software

G. Regulatory Information:
1. Regulation section:
   21CFR Sec.- 862.1345-Glucose test system.
   21CFR Sec.- 862.2100-Calculator/data processing module for clinical use.
2. Classification:
   II, I
3. Product code:
   NBW - System, Test, Blood Glucose, Over The Counter
   JQP - Calculator/Data Processing Module, For Clinical Use
4. Panel:
   Chemistry - 75

H. Intended Use:
1. Intended use(s):
   See Indication(s) for use below
2. Indication(s) for use:
   The PC care™ Blood Glucose Data Management Software is PC-based software intended for use in the home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for an effective diabetes management program. The PC care™ Blood Glucose Data Management Software connects to an i-SENS blood glucose meter, which comes with a PC care USB cable. The PC care™ Blood Glucose Data Management Software allows the user to download Blood glucose readings automatically from the meter to the PC.

3. Special conditions for use statement(s):
   Over-the-counter use
4. Special instrument requirements:
   i-SENS blood glucose meter with a PC care USB cable such as the CareSens II (k080923) and CareSens N (k083468).

I. Device Description:

The PC care™ Blood Glucose Data Management Software is an optional data management software for use only with the i-SENS Blood Glucose Meters. The PC care™ Blood Glucose Data Management Software allows the transfer of data from the i-SENS Blood Glucose Meters to a personal computer for enhanced data management using graphic displays and analysis tools of the device. Various graphic analysis tools in this software help users of i-SENS BGM system easily analyze the trends and changes in their blood glucose.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Agamatrix, Zero-Click Data Management System
2. Predicate 510(k) number(s):
   k062434
3. Comparison with predicate:
   Similarities:

Item	Device	Predicate (k062434)
Indications for Use	The PC care™ Blood Glucose Data Management Software is PC-based software intended for use in the home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for an effective diabetes management program.	Same
Software use indications	Single or Multiple user settings	Same
Program Installation	CD	CD
Computer System Requirements	CPU: Minimum 300MHz Intel Pentium 2 Windows 95, Windows 98, Windows ME, Windows 2000, Windows XP, Windows Vista and Windows 7	CPU: Minimum 700MHz Intel Pentium 2 Windows XP and Windows Vista

Item	Device	Predicate (k062434)
	Minimum free hard disk space: 60 MB	Same
About transmission:		
1. capable of uploading data from various devices	Software driver must be installed on PC	Same
2. Cable availability	USB	USB
3. Auto-detect COM port	Yes	Yes
About operation:		
1. Ability to access DMS program via icon or explorer	Yes	Yes
2. Viewing the User's manual	Yes	Yes
3. Ability to clear meter results in memory	No	No
4. Indication for primary test method	Not available	Not available
5. Ability to email report from PC directly from program	Yes	Yes
6. Time Block	Before/After Breakfast, Before/After Lunch, Before/After Dinner, Evening/Sleep Night	Same
About personal setting:		
1. Units of measure automatically set by country in setup installation	No	No
2. Ability to personalize target ranges	Yes	Yes
3. Ability to set default target range by diabetes type (Type I, Type II Gestational, etc.)	No	No
4. Default glucose target ranges available	Yes	Yes
5. Ability to enter hypoglycemic range	Yes	Yes
6. Ability to set default favorite report	Yes	Yes
7. Ability to enter insulin regiment	No	No
8. Change meter audio cues	No	No
About modifying results:		
1. Downloaded results cannot be edited or deleted	Yes	Yes

Item	Device	Predicate (k062434)
2. Manual data Entry 3. Ability to input additional information on patient and downloaded results 4. Deleting Results 5. Ability to modify meter average results 6. Ability to show cholesterol results/select units of measure	Allowed Yes-Health Profile, comments Only Manual entry results may be deleted Yes, 14, 30, 60 and 90 days or custom No	Allowed Yes- Meal tag, comments Only Manual entry results may be deleted Yes, 14, 30, 60 and 90 days or custom No
About patient and therapy management: 1. Required information on patient entry 2. Customizable schedule 3. Search patient capability 4. Search for specific patient in multiple (clinic) user function	 No Yes No No	 No Yes No No

Differences:

Item	Device	Predicate (k062434)
About transmission: Function that monitors the communication status	Yes	No
About operation: 1. Ability to set meter clock to a specific date and time 2. Copy saved database back to active DMS database 3. Copy database to separate file	 No No No	 Yes Yes Yes
About personal setting: 1. Units of measure display 2. Ability to change date format 3. Ability to synchronize meter clock to PC upon download 4. Ability to default to manufacturers setting (mealtime slots, target	 Choice of mg/dL or mmol/L mg/dL(default) No No No	 Automatically selected based on unit already set up in meter Yes (M-d-yy or d-M-yy) Yes Yes

Item	Device	Predicate (k062434)
glucose ranges, etc.) **5.** Ability to display 12 or 24 hour clock format	No	Yes
Report types:	Trend Graph, Average Analysis, Histogram, Target Analysis, Logbook, Statistics, Period Comparison Graph	Summary, Logbook, Target Analysis, Glucose Trend, Histogram, Average/Spread, Statistics
About modifying results: 1. Ability to specify complications associated with diabetes by patient 2. Specifying/Entering medications/insulin	Yes Yes, up to 3 different insulin type	No No
About patient and therapy management: 1. Diabetes Control 2. Doctor information 3. Deleting patients and all accompanying results 4. Insurance information 5. Hospital information 6. Ability to input additional information on patient	Yes (Insulin list, Medication list, Diet/Exercise options Yes No Yes Yes Yes-date of diagnoses, insulin, insulin date, dosage method, oral medication initial date, diet, exercise, working-non working day	No No Yes No No No

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

ISO15197:2003 - In vitro diagnostic test systems — Requirements for blood -glucose monitoring systems for self-testing in managing diabetes mellitus

L. Test Principle:

Data Transmission of whole blood glucose data from glucose meters

M. Performance Characteristics (if/when applicable):

The below performance characteristics as applicable, were presented in specific glucose meter clearances under k080923 and k083468

1. <u>Analytical performance:</u>

a. *Precision/Reproducibility:*
   See above statement under section M.
b. *Linearity/assay reportable range:*
   See above statement under section M.
c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
   See above statement under section M.
d. *Detection limit:*
   See above statement under section M.
e. *Analytical specificity:*
   See above statement under section M.
f. *Assay cut-off:*
   Not Applicable

2. Comparison studies:
   a. *Method comparison with predicate device:*
      See above statement under section M.
   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:
   See above statement under section M

N. Instrument Name:

PC care Blood Glucose Data Management Software

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__

CPU: Minimum 300MHz Intel Pentium 2

Windows 95, Windows 98, Windows ME, Windows 2000, Windows XP, Windows Vista and Windows 7

Minimum free hard disk space: 60 MB

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:

   Specimen identification is based on data transmitted from the meter.

4. Specimen Sampling and Handling:

   Data transmission from glucose meters using capillary whole blood samples

5. Calibration:

   Glucose meter specific See above statement under section M.

6. Quality Control:

   Glucose meter specific See above statement under section M.

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

The sponsor conducted bench testing for full memory download and rollover for data accuracy, using CareSens II and N meters and confirmed that data were transferred accurately in both tests and no other problems were detected.

In addition, 30 participants with varying demographics (age, sex, and education level) are included for consumer field testing study. The study was carried out with the participants who can read at a middle school level (8th grade of USA) of English. The user guide was used in the study (Flesch Kincaid Grade Level 5.7). All participants evaluated the usability of the PC care™ program to be above average on

a scale of 1 - 5 where 1 is difficult 3 is average and 5 easy.

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.