K083468

i-SENS, Inc.
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Special 510(k) SUMMARY

FEB 10 2009

(As required by 21.CFR.807.87)

Type of 510(k): Special

Submitter's Previously Cleared Device:

Name - **CareSens** Blood Glucose Monitoring System

510(k) number - **k080923**

Introduction: This 510(k) submission contains information/data on modifications made to submitter's previously cleared device. The modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device. The major modifications are the addition of an automatic code identification feature, and the user interface applications: alarms and post-meal flagging.

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Date Summary was Prepared: November 6, 2008

Device Name: Trade name: **CareSens N** Blood Glucose Monitoring System
Common Name: Blood Glucose Test System
Classification Name: Class II, 862.1345 Glucose Blood Tester

Predicate Device: We claim substantial equivalence to submitter's previously cleared CareSens Blood Glucose Monitoring System ("CareSens BGMS")

systems by i-SENS, Inc. (k080923) and the OneTouch® Ultra® Blood Glucose Monitoring System by LifeScan, Inc. (k024194).

Device Description: CareSens N Blood Glucose Monitoring System ("CareSens N BGMS") is an in vitro diagnostic device designed to measure the concentration of glucose in capillary whole blood with CareSens N Test Strips. The CareSens N model consists of the CareSens N meter (Model GM505IA, GM505IB, GM505IC: IA, IB and IC indicates the color of the devices, respectively, black, white, and light blue.), CareSens N test strips, and CareSens control solutions for two different glucose concentration ranges (called "Normal" and "Middle" ranges), lancing device, lancets, user manual, quick reference guide and a logbook.

Comparison to Submitter's Previously Cleared Device (k080923):

The glucose measurement test principle:	same as CareSens BGMS
Intended Use:	same as CareSens BGMS
Fundamental scientific technology:	same as CareSens BGMS

Modifications: **Automatic code identification by the meter through detection of a marked pattern on each strip, so that the user does not input code information.**

For the meter, the only difference is the addition of code identification sensors in the meter, while all other major electronic components are the same as those of CareSens BGMS. Please refer to Page 3 of Section 10 Specifications for details.

For the strip, the only difference is printing code-specific marks on the back side of each strip with infrared absorbing ink, while all the reagent components and measurement process are the same as those of CareSens BGMS. Please refer to Page11 of Section 10 Specifications for details.

Alarms (Three time set alarms, and 2-hour post meal alarm)

Post-meal flagging of test results

Number of Buttons on the meter is three

Common Features		
Item	**CareSens N BGMS**	**CareSens BGMS**
Enzyme	Glucose Oxidase	
Measurement principle	Amperometric method	
Test principle	Glucose Oxidase chemical reaction. The instrument measures the extent of current cause by presence of glucose in sample.	
Intended use	The test strips work with the device to quantitatively measure glucose in capillary whole blood. The test Strips are for *in vitro* (i.e., outside the body) diagnostic use only.	
Sample	Fresh capillary whole blood	
Electrode	Carbon	
Calibration	Plasma-equivalent	
Test Time (second)	5	
Sample volume (μL)	0.5	
Memory	250	
Test Range(mg/dL)	20~600	
Hematocrit range (%)	20~60 (below 400mg/dL)	
Glucose units	Either mg/dL or mmol/L	
Checking the system	Control solution	
Alternate Site Capability	Yes	
Operating Humidity	10~90%	
Differences		
Item	**CareSens N BGMS**	**CareSens BGMS**
Coding	Automatic code identification	Manual input by button
Self-diagnosis of code identification function	Yes	No
Three time set Alarms and 2-hour post-meal Alarm	Yes	No
Post-meal flagging	Yes	No
Number of buttons	3 buttons	2 buttons (CareSens II) 1 button (CareSens POP)

Since for CareSens N, the glucose measurement test principle, intended use, and fundamental scientific technology are the same as the submitter's unmodified device (k080923), there is no reason to expect that the performance would be different, but most of the performance evaluation tests done for the unmodified device were repeated to confirm that performance still satisfies the acceptance criteria. For performance evaluation, the following summary table shows the tests that were repeated.

Additionally, the substantial equivalence report for comparison to OneTouch® Ultra® is provided in Section 11.

Performance evaluation summary of modified device, CareSens N BGMS

The report numbers PE-01 to PE-17 in this table indicate those of the unmodified device (k080923), and the methods used for the tests can be found in that prior application. Please note that the actual reports for tests PE-01 to PE-17 that were repeated for CareSens N, are not included in this submission.

Report No.	Title	Pre-determined Acceptance Criteria		Results
PE-01	Repeatability Test	Concentration	Precision	Satisfactory
		<100 mg/dL	SD<7.7 mg/dL	
		≥100 mg/dL	CV<7.5%	
PE-02	Intermediate Precision test	Concentration	Precision	Satisfactory
		<100 mg/dL	SD<7.7 mg/dL	
		≥100 mg/dL	CV<7.5%	
PE-03	Linearity Study	linear response within 20~600mg/ dL		Satisfactory
PE-04-1	Shelf Lifetime Test for Test Strips (Before Opening)	N/A		These tests not repeated because all aspects of the strip chemistry are the same, and the marking on the back should not affect shelf life.
PE-04-2	Shelf Lifetime Test for Test Strips (After Opening)	N/A		
PE-05	System Accuracy Test (CareSens N vs. YSI)	Concentration	Accuracy	Satisfactory
		<75 mg/dL	within ±15 mg/dL	
		C≥75mg/dL	within ± 20%	

PE-06	Hematocrit Effect Test	Hct range: 20~60%; Bias (%): within ±15 %	Satisfactory
PE-07	Interference Test	Deviations are within ±15 % of the measurement for the samples with no interferent.	Satisfactory
PE-08	Substantial Equivalence	The distribution of test results in A-region of the Error Grid is over 95%.	Satisfactory
PE-09	Consumer Study	The distribution of test results in A-region of the Error Grid is over 95%.	Satisfactory
PE-10	Point-of-Care(POC) Study	The distribution of test results in A-region of the Error Grid is over 95%.	Satisfactory
PE-11	Temperature Study	Temp. range: 10~40℃; Bias (%): within ±10 %	Satisfactory
PE-12	Humidity Study	Humidity range: 10~90%; Bias (%): within ±10 %	Satisfactory
PE-13	Altitude Test	The distribution of test results in A-region of the Error Grid is over 95%.	Satisfactory
PE-14	Alternate site Study	The distribution of test results in A-region of the Error Grid is over 95%.	Satisfactory
PE-15	Drop Test	Height: 0.5, 1.0, 1.5m; Acceptance: within ±5 mg/dL	Satisfactory
PE-16	Vibration Test	RPM (50~60Hz): 300, 600, 1200; Acceptance: within ±5 mg/dL	Satisfactory
PE-17	Control solution	N/A	Test not repeated because the control solutions for both systems are the same.

Based on risk analysis provided in Section 14, the following validation activities were carried out and submitted in this application under the Section Numbers specified.

Validation Activities for Modified Features

The test reports in this table are included in this submission, and can be found under the Section Numbers below.

Section Numbers	Title	Pre-determined Acceptance Criteria	Results
12-1[1]	**Code Identification Test**	100% correct recognition of 15 types of code marks printed on the backside of the strip.	Satisfactory
12-2[2]	**Test of self-diagnosis of code identification**	The meter should recognize any malfunction in the code-reading sensors. If the code recognition sensor is faulty by any causes, meter should detect the malfunction and display Er6 message to prevent the user from reading inaccurate results.	Satisfactory
13 (TR-EI-15)[3]	**Alarm Test**	The meter should alarm at preset times within ±1 min.	Satisfactory
13 (TR-EI-16)	**Time Test**	The meter clock should display correct time within ±1 min after an extended period of observation (120 hours).	Satisfactory
13 (TR-EI-17)	**Data Average Test**	The averages (for 14-day, and before and after meal) calculated by meter software should be same as those calculated manually with spreadsheet.	Satisfactory
13 (TR-EI-18)	**ADC Function Test**	Within 2152 ~ 2406 (12bit ADC)	Satisfactory
13 (TR-EI-19)[4]	**Memory Test**	All test results saved on meter memory (as many as 250 data) should exactly match the manually recorded data.	Satisfactory

[1] Page 19 of Section 14 Risk analysis: H11-C11.2 Error of code recognition function
[2] Page 19 of Section 14 Risk analysis: H11-C11.1 Error (shorted or disconnected circuit) in the infrared photoreflectors for auto coding function
[3] Page 20 of Section 14 Risk analysis: H16 software
[4] Page 20 of Section 14 Risk analysis: H16 software-C16.3 Functional error of memory recall

15-1[5]	**Electromagnetic Compatibility Report**	It should meet the EMC test regulations given in p3 of the title report (Electronic Compatibility Report).	Satisfactory
15-2	**Electrical Safety Report**	It should comply with the test regulations given in p1 of the title report.	Satisfactory

Conclusion: All predetermined acceptance criteria were satisfied. The data also demonstrates that the CareSens N BGMS is substantially equivalent to the following predicate device systems:
k080923 - i-SENS, Inc. CareSens Blood Glucose Monitoring System
k024194 - LifeScan, Inc. OneTouch® Ultra® Blood Glucose Monitoring System

[5] Page 16 of Section 14 Risk analysis: H4 electromagnetic field compatibility

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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I-Sens, Inc.
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465-6 Wolgye-Dong, Nowon-Gu
Seoul, Republic of Korea 139-845

FEB 10 2009

Re: k083468
Trade Name: CareSens N Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: January 26, 2009
Received: January 26, 2009

Dear Hyun Joon Oh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

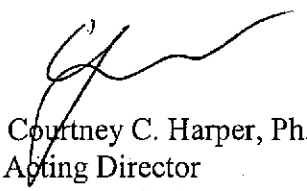
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostics Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K083468

Device Name: CareSens N Blood Glucose Monitoring System

Indication For Use: The CareSens N Meter is used for the quantitative measurement of glucose level in capillary whole blood as an aid in monitoring the effectiveness of diabetes management at home or in clinical settings. CareSens N Blood Glucose System should be used only for testing outside the body (in vitro diagnostic use only). Do not use the system for the diagnosis or screening of diabetes. Testing sites include the traditional fingertip testing along with alternate sites testing on forearm, palm, thigh and calf.

CareSens N Test Strip is used with the CareSens N Blood Glucose Meter for quantitatively measuring glucose in capillary whole blood. The CareSens N Test Strip is intended for self-testing outside the body (in vitro diagnostic use only). Do not use the system for the diagnosis of diabetes without the guidance of healthcare professional. Testing sites include the traditional fingertip testing along with alternate sites testing on forearm, palm, thigh and calf.

CareSens Control A&B Solutions are a red liquid to check that both the meters and test strips are working together properly. It contains a known range of glucose as written on the bottle.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Yuli May acting

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083468