k120759

JUN - 5 2012

510(k) Summary

(As required by 21 CFR 807.92)

Type of 510(k): **Special 510(k)**

Submitted By:
i-SENS, Inc.
465-6, Wolgye-dong, Nowon-gu, Seoul 139-845, Korea
Tel.) +82-2-916-6191
Fax) +82-2-942-2514
www.i-sens.com

Contact Person:
Dr. Hyun Joon Oh
Tel.) +82-33-903-0760
Fax) +82-33-748-6191
e-mail: hjoh@i-sens.com

Prepared Date: March 9, 2012

Device Name:
Trade name: **CareSens N Mini Blood Glucose Monitoring System**
Common Name: Glucose Test System

Regulatory Information:

1) Regulation section: 21 CFR 862.1345 Glucose Test System,
21 CFR 862.1660, Quality control material

2) Classification: Class II, Class I, reserved

3) Product Code: CGA - glucose oxidase, glucose
NBW - system, test, blood glucose, over the counter
JJX - Quality control material

4) Panel: Clinical Chemistry (75)

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

The CareSens Control Solutions are for use with the CareSens N Mini Meter and CareSens N Single Test Strips to check that the meter and the test strips are working together properly and that the test is performing correctly.

Device Description: The CareSens N Mini Blood Glucose Monitoring System (BGMS) measures the glucose level in whole blood samples using a small electrical current generated in the test strips. The system consists of the following: the CareSens N Mini Meter, CareSens N Single Test Strips, CareSens Control Solutions with two different glucose concentrations ("Control A" and "Control B" ranges, sold separately), Lancing Device, Lancets, User's Manual, Quick Reference Guide and Logbook.

Substantial Equivalence Information:

1) Predicate Device Name: **CareSens N Blood Glucose Monitoring System**

2) Predicate 510(k) Number: k083468

2) Comparison with Predicate Device:

The modified CareSens N Mini BGMS has the following features that are

same to the predicate device:

- intended use
- measurement principle
- fundamental scientific technology
- operating ranges

The modifications on the CareSens N BGMS to make a CareSens N Mini BGMS are:

- The meter appearance, the number of required batteries and memory capacity of the Meter
- Removal of the data transmission, data averaging and meter setting functions

The test strip is the same as that of the predicate system – the only difference is in the name (CareSens N Test Strip vs. CareSens N Single Test Strip).

Type of Test: Quantitative, Amperometric method, Glucose oxidase *(Aspergillus sp.)*

Test Principle: The reagent on the test strip produces a small electrical current using glucose as a substrate in the blood sample. The Meter converts the electrical current to a concentration of glucose.

Technological Characteristics: The CareSens N Mini BGMS has the same fundamental scientific technology as the predicate device.

Assessment of Performance Characteristics: The basic features of the CareSens N Mini BGMS are all the same with the predicate device except for the meter's appearance and output value (including the memory capacity). The CareSens N Mini BGMS uses the same test strips (just a different name) and control solutions being used in the CareSens N BGMS. So, its performance, safety and effectiveness have not changed from the predicate device. However, in order to confirm the modifications have not introduced any adverse effect validation testing including the meter function test and system accuracy test were conducted.

And to evaluate the usability the newly designed CareSens N Mini meter, the human factor study were conducted. The result indicates that the modified meter is as ease to use as the predicate device.

Summary of Pre-cleaning and Disinfection:

Disinfection studies were performed on the CareSens N Mini meter and lancing device by an outside commercial testing service to determine the robustness of the meter and lancing device to the recommended pre-cleaning and disinfection protocol, and its effectiveness in preventing the spread of blood-borne pathogens, using hepatitis B virus (HBV). CLOROX GERMICIDAL Wipes (EPA Reg. No: 67619-12) was validated for complete inactivation of live virus inoculated on the materials of the meter and lancing device. We have also demonstrated that 260 each of pre-cleaning and disinfection cycles designed to simulate 5 years of use has affected neither the performance nor on the external materials for the meter and lancing device.

Conclusion:

Based on the information provided in this submission, the CareSens N Mini BGMS is substantially equivalent to the predicate devices. A candidate device CareSens N Mini BGMS has met the performance, safety, and effectiveness of the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

i-SENS, Inc.
c/o Hyun Joon Oh
465-6 Wolgye-dong, Nowon-gu
Seoul
Republic of Korea 139-845

JUN - 5 2012

Re: k120759
Trade Name: CareSens N Mini Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: CGA, NBW, JJX
Dated: May 3, 2012
Received: May 8, 2012

Dear Dr. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K 120759

Device Name: CareSens N Mini Blood Glucose Monitoring System

Indications for Use:

The CareSens N Mini 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 CareSens N Mini 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 N Single Blood Glucose Test Strips are for use with the CareSens N Mini Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites.
The CareSens Control Solutions are for use with the CareSens N Mini Meter and CareSens N Single Test Strips to check that the meter and the test strips are working together properly and that the test is performing correctly.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

510(k) K 120759

Page 1 of 1