DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 19, 2017

I-SENS, INC.
JOON HO JUNG
RA TEAM MANAGER
43, BANPO-DAERO, 28-GIL, SEOCHO-GU
06646, SEOUL, KOREA

Re: K170614
Trade/Device Name: CareSens N Premier Monitoring System
CareSens N Premier BT Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW
Dated: September 18, 2017
Received: September 19, 2017

Dear Joon Ho Jung:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stayce Beck -A

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

k170614

Device Name

CareSens N Premier Monitoring System

Indications for Use *(Describe)*

The CareSens N Premier Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The CareSens N Premier Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) 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 Premier Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

k170614

Device Name

CareSens N Premier BT Monitoring System

Indications for Use *(Describe)*

The CareSens N Premier BT Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The CareSens N Premier BT Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) 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 Premier BT Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

(As required by 21 CFR 807.92)

Introduction: This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

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

510k Number k170614

Submitter Information:
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Contact Person: Joon Ho Jung

Prepared Date: February, 24th, 2017

Device Name
CareSens N Premier Blood Glucose Monitoring System
CareSens N Premier BT Blood Glucose Monitoring System

Classification Name Blood Glucose Test System

Product Code	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 Blood Glucose Test System	Clinical Chemistry 75

Predicate Device NoCoding1 Plus Blood Glucose Monitoring System, K160742.

Device Description CareSens N Premier brand of Blood Glucose Monitoring System is designed to have two variation models, CareSens N Premier BGMS and CareSens N Premier BT BGMS. CareSens N Premier BGMS is the models with all the changes implemented with exception to the addition of a Bluetooth module, whereas, CareSens N Premier BT BGMS is implemented with all of the changes stated in the submission. The two meters use the same CareSens N

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Single Test Strip and CareSens Control Solution. This Premarket Notification (510(k) is intended to demonstrate that the candidate devices to be marketed is safe and effective as the predicate device, NoCoding1 Plus Blood Glucose Monitoring System, K160742.

CareSens N Premier Blood Glucose Monitoring System and CareSens N Premier BT Blood Glucose Monitoring System consist of a blood glucose meter, single use test strips, and control solutions with two different glucose concentrations ("Control A" and "Control B" ranges).
The CareSens N Premier Blood Glucose Monitoring System and CareSens N Premier BT Blood Glucose Monitoring System is based on an electrochemical biosensor technology (electrochemical). The System measures the glucose level in whole blood samples using a small electrical current generated in the test strips. The following items are included in the system starter kit:

- 1 Blood Glucose Meter
- 10 Blood Glucose Test Strips
- 1 Lancing device
- 10 Lancets
- 1 Owner's Booklet
- 1 Quick Reference Guide
- 2 Batteries (3.0V lithium batteries)

The following items are compatible with the CareSens N Premier Blood Glucose Monitoring System and CareSens N Premier BT Blood Glucose Monitoring System and are available separately.

- CareSens N Single Blood Glucose Test Strips
- CareSens Glucose Control Solution

Intended Use:

The CareSens N Premier Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The CareSens N Premier Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) 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

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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 Premier Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.

The CareSens N Premier BT Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The CareSens N Premier BT Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) 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 Premier BT Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.

Comparison to the Cleared Device

The modifications are as below:

1. Change in the housing case of the meter
- Button positioning from the sides to the front of the meter (PC to Silicone Rubber).
- The material of the meter screen changed from PC to PMMA.
- Addition of ejection button (new material: POM).
- The material of the foot of the meter from TPU to TPE.
- Meter shell color
- Addition of backlight to meter screen

2. Trade name of the system changed from NoCoding1 Plus Blood Glucose Monitoring System to CareSens N Premier and CareSens N Premier BT Blood Glucose Monitoring System.

3. Addition of Bluetooth module to the meter for wireless data transfer to mobile devices (applies to GM01AAB only). The CareSens N Premier BT (GM01AAB) meter can communicate with smart devices such as a smart phone or a tablet by SmartLog App. The unmodified device K160742

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already had the data transfer function of transmitting the stored information to PC via a USB cable.

Other than these modifications, the following remains the same to the cleared device:

- Has the same intended use,
- Uses the same operating principle,
- Utilizes the same use environment and calibration method.

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Comparison to the Predicate Device

Characteristic	Predicate Device NoCoding1 Plus Blood Glucose Monitoring System, K160742	Candidate Device CareSens N Premier Blood Glucose Monitoring System CareSens N Premier BT Blood Glucose Monitoring System
Intended Use	The NoCoding1 Plus Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip. The NoCoding1 Plus Blood Glucose Monitoring System is intended for self-testing outside the body (for in vitro diagnostic use) 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 NoCoding1 Blood Glucose Test Strips are for use with the NoCoding1 Plus Blood Glucose Meters to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.	Same
Common name	System, test, blood glucose, over the counter	Same
Test Principle	Electro-chemical reaction. The glucose meter measures electrical current generated by enzyme using the glucose as substrate in sample.	Same
Enzyme	Glucose Oxidase - Glucose Oxidase (Aspergillus sp.): 2.7 units - Hexaaminеruthenium(III) chloride: 45.7 μg - Other ingredients: 1.6 μg	Same
Measurement Principle	Amperometric method	Same
Sample type	Fresh capillary whole blood	Same

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Calibration	Plasma-equivalent	Same
Coding system	No coding required (Automatic code identification)	Same
Test time (sec.)	5	Same
Sample volume (µl)	0.5	Same
Measurement unit	mg/dL	Same
Test range (mg/dL)	20-600	Same
Operating Humidity	10~90%	Same
Power Source	Two 3.0V lithium batteries (CR2032)	Same
Memory capacity	Up to 1,000 test results	Same
Test result average range	1, 7,14, 30 and 90 days (Pre-meal, Post-meal, Fasting and Total)	Same
Operating Temperature	42.8-111.2˚F	Same
Hematocrit range (%)	15~65	Same

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Performance Data

Non-clinical

Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the modified devices. The device passed all of the tests based on pre-determined Pass/Fail criteria.

Cleaning and Disinfection

The device is intended for single patient home use. Disinfection studies were performed on the meter and lancing device by an outside commercial testing service to evaluate effectiveness of disinfectant, CLOROX GERMICIDAL Wipes (EPA Reg. No: 67619-12), in preventing the spread of blood-borne pathogens, using hepatitis B virus (HBV). The results demonstrated 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 for meter with the same disinfectant designed to simulate 5 years (260 each of pre-cleaning and disinfection cycles for meter and lancing device) of single patient device use has no effect on the performance or the external materials of the meter and lancing device.

Conclusion

Based on the submitted information in this premarket notification, the candidate devices are substantially equivalent to the predicate device.