November 1, 2018

i-SENS, Inc.
Joon Ho Jung
RA Team Senior Manager
43, Banpo-daero 82-gil, Seocho-gu
Seoul, 06646
Korea

Re: K181273
Trade/Device Name: GLUCOCARD Shine Connex Blood Glucose Monitoring System,
GLUCOCARD Shine Express Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: October 2, 2018
Received: October 2, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181273

Device Name
GLUCOCARD Shine Express Blood Glucose Monitoring System

Indications for Use *(Describe)*
The GLUCOCARD Shine Express Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The GLUCOCARD Shine Express 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 GLUCOCARD Shine Blood Glucose Test Strips are for use with the GLUCOCARD Shine Express Blood Glucose Meters 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181273

Device Name
GLUCOCARD Shine Connex Blood Glucose Monitoring System

Indications for Use *(Describe)*
The GLUCOCARD Shine Connex Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The GLUCOCARD Shine Connex 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 GLUCOCARD Shine Blood Glucose Test Strips are for use with the GLUCOCARD Shine Connex Blood Glucose Meters 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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k181273

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)

Submitter Information:
i-SENS, Inc.
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Tel.) +82-2-910-0453
Fax) +82-2-942-2514
e-mail: jhjung@i-sens.com
Contact Person: Joon Ho Jung

Prepared Date: April 25th, 2017

Device Name GLUCOCARD Shine Connex Blood Glucose Monitoring System
GLUCOCARD Shine Express 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 CareSens N Premier Blood Glucose Monitoring System/CareSens N Premier BT Blood Glucose Monitoring System, K170614.

Device Description The GLUCOCARD Shine Connex Blood Glucose Monitoring System consist of a hand held GLUCOCARD Shine Connex Blood Glucose Meter, GLUCOCARD Shine Blood Glucose Test Strip, and GLUCOCARD Shine Glucose Control Solution. The GLUCOCARD Shine Express Blood Glucose Monitoring System consist of a hand held GLUCOCARD Shine Express Blood Glucose Meter, GLUCOCARD Shine Blood Glucose Test Strip, and GLUCOCARD Shine Glucose Control Solution.

The two candidate test systems are derived from the same design platform as their predicate device, CareSens N Premier Blood Glucose Monitoring System/CareSens N Premier BT Blood Glucose Monitoring System (K170614). The candidate devices are modified versions of the predicate device to suit the market needs for test systems with Bluetooth and talking features. The GLUCOCARD Shine Connex Blood Glucose Meter is a Bluetooth meter, similar to the CareSens N Premier BT Blood Glucose Meter, whereas the GLUCOCARD Shine Express Blood Glucose Meter is enabled with a talking feature (English and Spanish).

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Both candidate devices are used with the GLUCOCARD Shine Blood Glucose Test Strip and GLUCOCARD Shine Glucose Control Solution, which are the same in chemical composition, fundamental scientific technology, intended use and operating principle as with the components of the predicate device, cleared in K170614. The only difference between the test strip & control solution of the candidate device and the ones of the predicate device is the brand name.

Intended Use:

GLUCOCARD Shine Connex BGMS:
The GLUCOCARD Shine Connex Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The GLUCOCARD Shine Connex 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 GLUCOCARD Shine Blood Glucose Test Strips are for use with the GLUCOCARD Shine Connex Blood Glucose Meters to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.

GLUCOCARD Shine Express BGMS:
The GLUCOCARD Shine Express Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The GLUCOCARD Shine Express 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 GLUCOCARD Shine Blood Glucose Test Strips are for use with the GLUCOCARD Shine Express Blood Glucose Meters to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.

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Comparison to the Predicate Device

Characteristic	Predicate Device (K170614) CareSens N Premier BGMS CareSens N Premier BT BGMS	Candidate Device GLUCOCARD Shine Connex BGMS GLUCOCARD Shine Express BGMS
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 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.	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 candidate devices are 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 cleaning and disinfection cycles for meter with the same disinfectant designed to simulate 5 years (260 each of 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.