December 13, 2017

i-SENS, Inc.
Joon Ho Jung
RA Team Manager
43, Banpo-daero 28-gil, Seocho-gu
Seoul, 06646
Korea

Re: K171480
Trade/Device Name: NoCoding1 Plus Blood Glucose Monitoring System
VeraSens Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: November 10, 2017
Received: November 13, 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 Part 801 and Part 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.

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.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171480

Device Name
NoCoding1 Plus Blood Glucose Monitoring System

Indications for Use *(Describe)*
The NoCoding1 Plus Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The NoCoding1 Plus 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 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.

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)*
K171480

Device Name
VeraSens Blood Glucose Monitoring System

Indications for Use *(Describe)*
The VeraSens Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The VeraSens 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 VeraSens Blood Glucose Test Strips are for use with the VeraSens 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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k171480

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:
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Contact Person: Joon Ho Jung

Prepared Date: December 13, 2017

Device Name **NoCoding1 Plus Blood Glucose Monitoring System**
VeraSens 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 The NoCoding1 Plus BGMS and VeraSens BGMS is a derivation from the same design file as its predicate device, NoCoding1 Plus Blood Glucose Monitoring System with the addition of a Bluetooth module. 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.

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The NoCoding1 Plus BGMS and VeraSens BGMS 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 NoCoding1 Plus BGMS and VeraSens BGMS 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 NoCoding1 Plus and VeraSens Blood Glucose Monitoring system:

- 1 NoCoding1 Plus (VeraSens) Blood Glucose Meter
- 10 NoCoding1 (VeraSens) 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 the NoCoding1 Plus BGMS and VeraSens BGMS and are available separately.

NoCoding1 brand
- NoCoding1 Blood Glucose Test Strips
- NoCoding1 Glucose Control Solution

VeraSens brand
- VeraSens Blood Glucose Test Strips
- VeraSens Glucose Control Solution

Intended Use

NoCoding1 Plus BGMS: The NoCoding1 Plus Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The NoCoding1 Plus 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.

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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.

Intended Use

VeraSens BGMS:

The VeraSens Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The VeraSens 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 VeraSens Blood Glucose Test Strips are for use with the VeraSens Blood Glucose Meters 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. Addition of Bluetooth module to the meter for wireless data transfer to mobile devices. The NoCoding1 Plus (VeraSens) meter can communicate with smart devices such as a smart phone or a tablet by SmartLog App. The unmodified device K160742 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** **NoCoding1 Plus Blood Glucose Monitoring System** **VeraSens 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. The NoCoding1 Glucose Control Solutions are for use with the NoCoding1 Plus Blood Glucose Meters and NoCoding1 Blood Glucose Test Strips to check that the meter and the test strips are working together properly and that the test is performing correctly.	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	Same

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	- Hexaaminеruthenium(III) chloride: 45.7 µg - Other ingredients: 1.6 µg	
Measurement Principle	Amperometric method	Same
Sample type	Fresh capillary whole blood	Same
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
Control Levels	Two Levels (A and B)	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
Data communication	USB cable	USB cable, Bluetooth

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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.

Cybersecurity Risk Analysis Summary

Potential Hazard	Potential cause(s)	Severity (Pre/ Post)	Likelihood (Pre/Post)	Risk (Pre/Post)	Controls (Counter measure)	Risk/Benefit Analysis	Test ID	Completeness of risk control
H2 User errors and/or unawareness	The user may experience inconvenience from the newly designed meter.	Minor/ Minor	Probable/ Remote	AFAP/ACC	Human Factor Study	When user fails to recognize the modified housing features, there is a risk of user inconvenience. Therefore, human factor study was done to verify the user convenience of using the meter. Although the residual risk still exists, it is not in the non-acceptable region. The benefit of the meter is to enable the user to manage their glucose level. It ultimately contributes to the user's health. Therefore the benefits outweigh this risk.	* BGM-027B-R009_Human Factor Study Report _(Section 012)	Completed

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Potential Hazard	Potential cause(s)	Severity (Pre/ Post)	Likelihood (Pre/Post)	Risk (Pre/Post)	Controls (Counter measure)	Risk/Benefit Analysis	Test ID	Completeness of risk control
H25 Cybersecurity problem	Bluetooth connection between meter and unintended device	Minor/ Minor	Occasional/ Remote	AFAP /ACC	Restriction on display time of showing Passkey	When Bluetooth connection between the meter and unintended device is complete, there is a risk that user can be damaged by cybersecurity problem. Therefore, Passkey entry and short display time of showing Passkey was adopted to prevent that situation and software function test was done to verify this. Also counter measure to lower probability of the risk has been done by adding explanation in user manual. The meter was designed meeting Bluetooth SIG standard and it was described in Bluetooth communication protocol. Therefore the residual risk falls from AFAP to ACC region. Although the residual risk still exists, it is not in the non-acceptable region. The benefit of the meter is to enable the user to manage their glucose level. It ultimately contributes to the user's health. Therefore the benefits outweigh this risk.	BGM-018B-R021_Software Function Test (Section 016)	Completed
H25 Cybersecurity problem	Data transmission without data encryption	Minor /Minor	Remote /Improbable	ACC /ACC	Product design which meets Bluetooth SIG standard	When data is exposed while meter transmits the data, there is a risk that user can be damaged by cybersecurity problem. Therefore the meter was designed meeting Bluetooth SIG standard and it was described in Bluetooth communication protocol. Also, Bluetooth SIG certification was received. This verifies that	Bluetooth SIG certification	Completed

Potential Hazard	Potential cause(s)	Severity (Pre/ Post)	Likelihood (Pre/Post)	Risk (Pre/Post)	Controls (Counter measure)	Risk/Benefit Analysis	Test ID	Completeness of risk control
						Bluetooth met data security goals. Although the residual risk still exists, it is not in the non-acceptable region. The benefit of the meter is to enable the user to manage their glucose level. It ultimately contributes to the user's health. Therefore the benefits outweigh this risk.		
H25 Cybersecurity problem	Outside intrusion during UART communication	Minor /Minor	Occasional /Remote	AFAP /ACC	Connect with a device using the protocol designed by i-SENS, Inc. (BGM-TCF-14-025_Communication Protocol for UART)	Outside intrusion during UART communication, there is a risk that user can be damaged. To reduce the risk, the meter connects with other device one-to-one and only use the communication protocol designed by i-SENS, Inc. Therefore the residual risk falls from AFAP to ACC region. Although the residual risk still exists, it is not in the non-acceptable region. The benefit of the meter is to enable the user to manage their glucose level. It ultimately contributes to the user's health. Therefore the benefits outweigh this risk.	User Manual pg. 10, 41	Completed
H16 Software problem	Error of download function using UART communication	Minor	Occasional/ Remote	AFAP/ ACC	Memory Test	When software fails to download the data properly, there is a risk of user inconvenience. Therefore, memory test was done to verify the memory function of the meter and lower the probability of the risk. Therefore the residual risk falls from AFAP to ACC region Although the residual risk still exists, it is not in the non-acceptable region. The benefit of the	BGM-027B-R023_3_Memory Test	Complete

Potential Hazard	Potential cause(s)	Severity (Pre/ Post)	Likelihood (Pre/Post)	Risk (Pre/Post)	Controls (Counter measure)	Risk/Benefit Analysis	Test ID	Completeness of risk control
						meter is to enable the user to manage their glucose level. It ultimately contributes to the user's health. Therefore the benefits outweigh this risk.		
H4 Electromagnetic field compatibility	Electromagnetic field effect during Bluetooth communication	Minor /Minor	Occasional /Remote	AFAP /ACC	EMC test report Caution indication (Manual)	When meter is exposed to electromagnetic field, there is a risk of meter's damaging and malfunction. Therefore, counter measure to lower the probability of the risk has been done by adding related caution indication phrase in the user manual. Therefore the residual risk falls from AFAP to ACC region. Although the residual risk still exists, it is not in the non-acceptable region. The benefit of the meter is to enable the user to manage their glucose level. It ultimately contributes to the user's health. Therefore the benefits outweigh this risk.	EMC Test report (NK-15-E-0779) Caution indication (Manual)	Complete
H4 Electromagnetic field compatibility	Electromagnetic field effect during Bluetooth communication	Minor	Occasional/ Remote (2)	AFAP/ ACC	SIG Certificate FCC Part 15 Subpart B & Part 2 EMC Safety Test IEC 60601-1-2: 2007, EN 60601-1-2:2007/AC:2010 IEC 61010-	When meter is exposed to electromagnetic field, there is a risk of meter's damaging and malfunction. Therefore, R&TTE and FCC test was done to verify that there is no problem of meter's electromagnetic field effect and lowers the probability of the risk. Also, counter measure to lower the probability of the risk has been done by adding related caution indication phrase in the user manual. Therefore the residual risk falls from AFAP to ACC region. Although the residual	Qualified SIG Design ID: 78922 FCC (NK-15-E-0781(i-Sens_GM01BAB)_FCC) EMC (NK-15-E-0779) Safety (KR-KETI2885)	Complete

Potential Hazard	Potential cause(s)	Severity (Pre/ Post)	Likelihood (Pre/Post)	Risk (Pre/Post)	Controls (Counter measure)	Risk/Benefit Analysis	Test ID	Completeness of risk control
					1:2010, IEC 61010-2-101:2015	risk still exists, it is not in the non-acceptable region. The benefit of the meter is to enable the user to manage their glucose level. It ultimately contributes to the user's health. Therefore the benefits outweigh this risk.		
H2 User errors and/or unawareness	Difficulties of performing Bluetooth pairing process	Minor	Probable Remote	AFAP ACC	Use instruction	When user fails to transfer meter data to his/her device via Bluetooth connection, there is a risk of user inconvenience. Therefore, counter measure to lower the probability of the risk has been done by adding use instruction in the user manual. Therefore the residual risk falls from AFAP to ACC region. Although the residual risk still exists, it is not in the non-acceptable region. The benefit of the meter is to enable the user to manage their glucose level. It ultimately contributes to the user's health. Therefore the benefits outweigh this risk.	User manual, pg. 37 Additional Bluetooth pairing quick guide (Proposed labeling)	Complete
H16 Software problem	Error of download function using Bluetooth communication	Minor	Occasional Remote	AFAP ACC	Memory test	When software fails to download the data properly, there is a risk of user inconvenience. Therefore, memory test was done to verify the memory function of the meter and lower the probability of the risk. Therefore the residual risk falls from AFAP to ACC region Although the residual risk still exists, it is not in the non-acceptable region. The benefit of the meter is to enable the user to manage their glucose level. It ultimately	BGM-027B-R023_3_Memory Test	Complete

Potential Hazard	Potential cause(s)	Severity (Pre/ Post)	Likelihood (Pre/Post)	Risk (Pre/Post)	Controls (Counter measure)	Risk/Benefit Analysis	Test ID	Completeness of risk control
						contributes to the user's health. Therefore the benefits outweigh this risk.		

Conclusion

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