DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 16, 2016

I-SENS, INC.
JOON HO JUNG
RA TEAM MANAGER
43, BANPO-DAER0 28-GIL, SEOCHO-GU
SEOUL 06646
KR

Re: k160742
Trade/Device Name: NoCoding1 Plus Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: November 18, 2016
Received: November 29, 2016

Dear Mr. 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,

Courtney H. Lias -S

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)*
K160742

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 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.

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.

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510(k) Summary

(As required by 21 CFR 807.92)
k160742

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Type of 510(k): Traditional 510(k)

Submitter Information:
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Contact Person: Joon Ho Jung

Prepared Date: December 12th, 2016

Device Name and Classification
Trade names: NoCoding1 Plus Blood Glucose Monitoring System
Common 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
CGA	Class II	21 CFR 862.1345 Blood Glucose Test System	Clinical Chemistry 75
*JJX	Class I	21 CFR 862.1660 Blood Glucose Test System	Clinical Chemistry

***Regulatory approval** Control solution has been cleared under k080923, CareSens Blood Glucose Monitoring System. The CareSens BGMS is manufactured by i-SENS, and has the same technological principals as to the candidate device. CareSens control solution is exactly the same as the NoCoding1 control solution in exception to the brand name. Both control solution has the exact same manufacturing process, and chemical formulation & composition.

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Predicate Device CareSens N Blood Glucose Monitoring System (k083468)

Device Description

The NoCoding1 Plus Blood Glucose Monitoring System (BGMS) consists 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 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 Blood Glucose Monitoring system:

- 1 NoCoding1 Plus Blood Glucose Meter
- 10 NoCoding1 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 NoCoding1 Plus BGMS and are available separately.
NoCoding1 Glucose Control Solution (cleared in k080923)

Intended Use:

NoCoding1 Plus Blood Glucose Monitoring System

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.

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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.

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Comparison to the Predicate Device

Characteristic	**Predicate Device** **CareSens N Blood Glucose Monitoring System (k083468)**	**Candidate Device** **NoCoding1 Plus Blood Glucose Monitoring System**
Intended Use	The CareSens N 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 Blood Glucose Monitoring System is intended for self- testing outside the body (*in vitro*) by people with diabetes as an aid to monitor the effectiveness of diabetes control. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.	Same with the following difference: No alternative site testing
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

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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	Same
Power Source	Two 3.0V lithium batteries (CR2032)	Same
Differences		
Memory capacity	Up to 250 test results	Up to 1,000 test results
Test result average range	14 days (Pre-meal, Post-meal, and Total)	1, 7,14, 30 and 90 days (Pre-meal, Post-meal, Fasting and Total)
Operating Temperature	50 - 104 ˚F	42.8-111.2˚F
Hematocrit range (%)	20~60	15~65
Alternate site capability	Yes (Testing sites include the traditional fingertip testing along with alternate sites testing on forearm, palm, thigh and calf.)	No

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Performance Test Summary

Repeatability Test

The repeatability of NoCoding1 Plus BGMS was evaluated using whole blood spiked with glucose at five concentration intervals. Blood glucose is measured by the same user, same meters and same strip lots in one day. The repeatability is evaluated for a total of 5 concentration intervals using 10 meters per lot and 3 lots of test strips. The pooled SD of concentration intervals 1 and 2 were 1.9 and 2.1 mg/dL, respectively that were below 5.0 mg/dL. The pooled CV % of concentration intervals 3, 4 and 5 were 2.8, 2.6 and 3.2 %, respectively that were below 5.0 %. All three lots met the acceptance criteria of the repeatability test in all concentration intervals.

Intermediate Precision

Intermediate precision was performed using control solution with 10 operators. Three lots of test strips were evaluated. Glucose testing was conducted by every operator using 3 levels of control solutions for a minimum of 10 days. The pooled SD of concentration interval 1 was 1.4 mg/dL and the pooled CV of concentration intervals 2 and 3 were 3.0 %, 2.4 % respectively. NoCoding1 Plus have met the acceptance criteria of intermediate precision requirements.

Linearity Test

The linearity of NoCoding1 Plus BGMS was evaluated using whole blood spiked with glucose. Linearity is evaluated for a total of 9 concentration intervals using 5 meters per lot and 3 lots of test strips. Each meter is tested once with each concentration. Three lots of test strips were tested to confirm linearity of NoCoding1 Plus BGMS throughout its measuring range of 20 to 600 mg/dL. All data points are within ±10 mg/dL for glucose concentrations <100 mg/dL and within 10% for glucose concentrations ≥100 mg/dL. Precision was maintained under 5 mg/dL for glucose concentrations <100 mg/dL (SD values) and 5 % for concentrations ≥100 mg/dL (CV values). The linear correlation coefficients (r2) for all strip lots were well above the acceptance criteria of 0.98. within the measured range of 13.1 to 614 mg/dL, over the specification of the measuring range, the performance of test strips has been confirmed to be linear.

Hematocrit Effect Test

Seven different hematocrit levels were tested to evaluate the effect of hematocrit level on measurement of glucose concentration. Each of three different glucose intervals is prepared in seven different hematocrit levels. Three concentration levels of blood samples at seven hematocrit levels were tested for three lots of test strips. For all of the 21 samples, the biases of individual BGMS measurements from YSI were less than 10 mg/dL and 10% below 80 mg/dL and above 100 mg/dL respectively. Hence it has been confirmed that NoCoding1 Plus BGMS has no significant interference within 15 % to 65 % hematocrit levels.

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Interference Test

Interference test results have shown that the 24 interferents studied (acetaminophen, ascorbic acid, bilirubin, cholesterol, creatinine, dopamine, EDTA, galactose, gentisic acid, glutathione (Red), hemoglobin, heparin, ibuprofen, icodextrin, L-dopa, maltose, methyldopa, pralidoxime iodide, salicylate, tolazamide, tolbutamide, triglycerides, uric acid and xylose) at significantly high levels have no effect on glucose measurement by NoCoding1 Plus BGMS. The results obtained from the primary tests were sufficient to show non-significance of the presence of these interferents at both low and high glucose concentration intervals. Thus it can be concluded that NoCoding1 Plus BGMS is safe to use for blood glucose monitoring even in the presence of the 24 substances studied.

Altitude Test

Altitude testing is performed inside an altitude chamber where various altitudes are simulated by manipulating the atmospheric pressure inside the chamber. Individual results from NoCoding1 Plus BGMS did not show significant difference (± 10 %) with respect to the reference equipment, nor with different altitudes at all glucose concentrations. Hence it was confirmed that our BGMS has no systematic response to altitudes and is not significantly affected by lack of atmospheric oxygen up to 10,000 feet (3,048m) above the sea level.

Operating Condition Test

The operating conditions of NoCoding1 Plus BGMS are within 6℃ to 44℃ and 10 % to 90 % (RH). The test is conducted at 9 different combined temperature and humidity conditions. By evaluating measurement difference from the condition 5 (23℃, 40%) & individual meter value compared to YSI, the performance of NoCoding1 Plus BGMS is demonstrated to be uniformly accurate throughout the actual conditions of use. Operating condition test was conducted at 9 combined temperature-humidity conditions of 6 ℃, 23 ℃ and 44 ℃ at 10%, 40% and 90% RH. We have confirmed that NoCoding1 Plus BGMS operates normally at the presented conditions, individual meter measurements giving less than 10 mg/dL or 10 % bias from YSI reference results.

Sample volume Test

Minimum sample volume for accurate glucose measurement was determined by testing with whole blood samples. Sample volume test was performed using whole blood samples from 3 subjects, each divided into hypoglycemic, euglycemic and hyperglycemic concentrations. When 0.4 µL of sample was applied to the strip, Er 4 messages appeared. The smallest volume required for accurate measurement of NoCoding1 Plus BGMS was 0.5 µL, and the meter bias from YSI were all within the acceptance criteria.

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User Performance

In this study, diabetic and pre-diabetic people from various backgrounds have participated in the user performance test of NoCoding1 Plus BGMS. The study is monitored at three clinical sites against a total of 371 test participants. Approximately ten percent of (10%) but no more than fifteen percent (15%) of naïve subjects have participated in the study. The measurement results have demonstrated that 100 % of data have met the Primary and Reference criteria. Test subjects varied in gender, age and highest level of education, and regardless of the backgrounds, more than 100% of subjects had given scores above 3 (neither easy nor difficult) on the questionnaire. While few of the test subjects were prediabetic and were never exposed to using BGMS on their own, the test results confirm that the instruction given in the User's Guide of NoCoding1 Plus BGMS is easy to follow and that it is easy to use for blood glucose testing.

Accuracy results for glucose concentration < 75 mg/dL

Site	n	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Combined	41	61.0% (25/41)	97.6% (40/41)	100% (41/41)

Accuracy results for glucose concentration ≥ 75 mg/dL

Site	n	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Combined	330	70.0% (231/330)	96.1% (317/330)	100% (330/330)	100% (330/330)

Linear regression analysis

Site	Slope	Intercept	R^2	N	Glucose Concentration range (new meter) (mg/dL)
Combined	1.0223	-1.3686	0.9934	371	48~553

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Summary of Pre-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 10,950 each of pre-cleaning and disinfection cycles for meter with the same disinfectant designed to simulate 3 years of multiple-patient use or 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.

Data demonstrating substantial equivalence	The candidate device was tested in accordance with ISO 15197. Analytical performance testing included system accuracy, repeatability, and intermediate precision testing. A user performance evaluation assessed accuracy of results and usability of the device in the hands of intended users. The candidate device performed similarly to both the predicate device as well as to a laboratory comparator method, the Yellow Springs Instrument (YSI). All testing demonstrated safety and effectiveness of the candidate device and substantial equivalence to the predicate device. Therefore, there are no substantive differences between the products defined in this 510(k) submission and the predicate device.
Conclusion	Based on the submitted information in this premarket notification, the candidate devices are substantially equivalent to the predicate device. Further, the candidate devices have met the performance, safety, and effectiveness of the device for its intended use.