August 31, 2018

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

Re: K180866
Trade/Device Name: CareSens S Fit Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: March 26, 2018
Received: April 2, 2018

Dear Joon 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,

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)*
K180866

Device Name
CareSens S Fit Blood Glucose Monitoring System

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

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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): Traditional 510(k)
Assigned 510(k) Number: k180866

Submitter Information:
i-SENS, Inc.
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Contact Person: Joon Ho Jung

Prepared Date: July 26, 2018

Device Name **CareSens S Fit 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 and CareSens N Premier BT Blood Glucose Monitoring System (k170614).

Device Description The CareSens S Fit BGMS is a derivation from the same design file as its predicate device, CareSens N Premier and CareSens N Premier BT Blood Glucose Monitoring System, utilizing a new test strip. This Premarket Notification (510(k) is intended to demonstrate that the candidate devices to be marketed is safe and effective as the predicate device.

The CareSens S Fit BGMS consists of a blood glucose meter, single use test strips, and control solutions with two different glucose concentrations ("Level 1" and "Level 2" ranges). The CareSens S Fit 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 CareSens S Fit BGMS Blood Glucose Monitoring system:

- 1 CareSens S Fit Blood Glucose Meter
- 10 CareSens S Blood Glucose Test Strips
- 1 Lancing device
- 10 Lancets

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- 1 Owner’s Booklet
- 1 Quick Reference Guide
- 1 Battery (3.0V lithium battery)

The following items are compatible with the CareSens S Fit BGMS and are available separately.

- CareSens S Blood Glucose Test Strips
- CareSens S Glucose Control Solution

Intended Use CareSens S Fit BGMS:

The CareSens S Fit Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The CareSens S Fit 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 S Blood Glucose Test Strips are for use with the CareSens S Fit 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

The similarities and differences between the predicate device (K160742) and the candidate device are highlighted in Tables 1 and 2 below.

Table 1: Similarities between the Candidate and Predicate Device

Characteristic	Predicate Device CareSens N Premier Blood Glucose Monitoring System, K170614	Candidate Device CareSens S Fit Blood Glucose Monitoring System
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 (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 CareSens N 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 - Hexaammineruthenium(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
Sample volume (µl)	0.5	Same
Measurement unit	mg/dL	Same
Operating Humidity	10~90%	Same
Control Levels	Two Levels (A and B)	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
Hypoglycemia indicator	Yes	Same
Expiration date indicator	Yes	Same
Data communication	USB cable	Same

Table 2: Differences between the Candidate and Predicate Device

Characteristic	**Predicate Device CareSens N Premier Blood Glucose Monitoring System, K170614**	**Candidate Device CareSens S Fit Blood Glucose Monitoring System**
Test time (sec.)	5	6
Test range (mg/dL)	20-600	40-600
Operating Temperature	42.8-111.2˚F	50-104 ˚F
Power Source	Two 3.0V lithium batteries (CR2032)	One 3.0V lithium battery (CR2032)
Hematocrit range (%)	15-65	20-60
Hyperglycemia indicator	No	Yes

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Performance Test Summary

Within-Run Precision Evaluation
Within-run precision is determined using venous whole blood samples altered by spiking, diluting and by allowing glycolysis. For each sample concentration, 10 meters and 500 test strips from 10 vials of 3 manufacturing lots are used. Test strips are taken from the same vial for each meter. For each glucose concentration range, the mean value, standard deviation (with 95% confidence intervals) and percent CV are calculated. It was confirmed that the CareSens S Fit SMBG test system meets the acceptance criteria.

Intermediate Precision Evaluation
Intermediate precision is determined using control solutions. For each sample concentration, 10 meters and 500 test strips from 10 vials of 3 manufacturing lots are used. Test strips are taken from the same vial for each meter. For each glucose concentration range, the mean value, standard deviation (with 95% confidence intervals) and percent CV are calculated. The pooled SD of concentration interval 1 and 2 were 0.8 mg/dL and 1.5 mg/dL respectively, and pooled CV of interval 3, 4 and 5 were 2.8%, 3.2% and 4.0%. The results have met the acceptance criteria of intermediate precision requirements of the FDA SMBG Guidance (2016).

Linearity Evaluation
The linearity study includes an evaluation of 11 evenly spaced concentrations of blood samples, and the results are analyzed according to “Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach”, CLSI document EP6-A. Linearity test was conducted using meters with altered firmware that shows numerical response at concentrations that would normally display “Low” and “High” error messages at the two extreme ends of concentrations. The correlation coefficient, y-intercept, slope of the regression line were obtained, and by fitting a regression line to the data, the best polynomial fit of the data were determined. All of the three strip lots’ results were confirmed to be in linear relationship with the reference values.

Method Comparison/User Performance
Following the FDA SMBG Guidance, at least 350 different subjects participated in the user evaluation of the Self-Monitoring Blood Glucose Test Systems in comparison to YSI 2300 STAT Plus glucose analyzer as a reference equipment. The method comparison/user evaluation study is designed for the assessment of both system accuracy in the hands of the intended users as well as other aspects to support lay-use, such as a labeling assessment and usability. A Method Comparison/User Evaluation study was conducted for the CareSens S Fit SMBG test system, in which 376 subjects participated. The measurement results demonstrated that 98.1% of data were within ± 15% and 100% of data were within ± 20% bias relative to the reference measurement method. For the questionnaire, more than 95% of subjects have given scores of 3 and above to each of the questions. It is concluded that most of the intended users will be able to understand the user manual and will be able to perform self blood glucose testing with no difficulty.

Additional Accuracy at Extreme Glucose Values Report
Additional accuracy study is conducted to provide a robust evaluation of SMBG performance in the extreme upper (greater than 250 mg/dL) and lower ends (less than 80 mg/dL) of the claimed measuring range.

For the evaluation of the CareSens S Fit SMBG Test System’s performance in the extreme upper and lower

ends, the measurement results of modified capillary blood samples were analyzed. The results satisfied the accuracy criteria in the FDA guidance for method comparison analysis.

Interfering Substance Evaluation

The effect of potentially interfering endogenous and exogenous substances and conditions such as icterus, lipemia and the effect of common medications are tested to demonstrate that these substances do not interfere with the CareSens S Fit SMBG test system. Interference testing is performed using samples containing various glucose concentrations to evaluate clinically relevant decision points

52 potentially interfering substances were studied for their interfering effects on the blood glucose measurements of CareSens S Fit SMBG. All of the substances were tested at FDA recommended test concentrations except for gentisic acid and maltose. The results obtained from the primary tests were sufficient to show non-significance of the presence of these interferents at all three blood glucose concentration intervals. However, dose response test was performed for Hemoglobin and the maximum concentration at which these substances have no effect on the CareSens S Fit SMBG test system was 17.7 g/dL.

Hematocrit Effect Test

The hematocrit interference is tested at five glucose intervals. Specific percentages of hematocrit is achieved by manipulating the plasma to packed cell ratio following centrifugation. Hematocrit levels tested span the claimed range in 5% intervals.

Five concentration levels of blood samples at nine hematocrit levels were tested for three lots of test strips. For all of the nine samples in interval 1, the bias of measurement was within ±10 mg/dL. For all of the 36 samples in intervals 2 ~ 5, the bias of measurements was within ±8% on average, all individual values were within ±15% relative to the comparator method. Hence, it has been confirmed that CareSens S Fit BGMS has no interference within 20% to 60% hematocrit level.

Accelerated Stability Test

The purpose of the accelerated stability test using open vial test strips is to estimate the lifetime of test strips after opening the vials. The strip vials are stored at several high temperatures, and the vials are opened at every testing point. The Arrhenius equation is used to calculate for the predicted lifetime. The stability test protocol was designed from documentation CLSI EP25-A, ‘Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. All 3 lots of test strips are predicted to have in-use stability of 5.5 months minimum. The real-time stability test for open vial strip lots is ongoing and the shelf life study will be conducted for more than 25 months.

Test Strip Stability Test (Before Opening)

The purpose of shelf-life test before opening vial (shelf life stability) is to study the stability of test strip under recommended storage conditions before the strip bottles have been opened. Precision and accuracy evaluation is conducted once in every 1~3 month’s interval using for 25 months. At every testing point, strip vials are removed from the designated storage conditions. Accuracy evaluation is performed and analyzed by computing measurement bias from the reference values (YSI 2300 STAT Plus glucose analyzer) and precision study is analyzed by computing the SD and CV. Precision evaluation by control solution is conducted over 5 days.

The test strip stability study was conducted for 462 days (before opening vial) using three strip lots at five storage

conditions. Precision study was assessed by evaluating the SD and CV using blood samples measurement values as well as control solutions measurement values. The SD and CV values were within the acceptance criteria for all the three lots at all storage conditions. Accuracy study was also conducted. At each testing point, 24 distinct samples were measured by CareSens S Fit SMBG test system and for all of the 360 data points, the bias of meter measurement value against the reference results (YSI 2300 STAT Plus) was within the acceptance criteria.

Test Strip Stability Test (After Opening)
The purpose of shelf-life test after opening vial (in-use stability) is to study the stability of test strip under recommended storage conditions after the strip bottles have been opened. At every testing point, strip vials are removed from the designated storage conditions. Accuracy evaluation is performed and analyzed by computing measurement bias from the reference values (YSI 2300 STAT Plus glucose analyzer) and precision study is analyzed by computing the SD and CV. Precision evaluation by control solution is conducted over 5 days.

Stability of open vial test strip have been conducted by grouping the strip use frequency into the four categories. The tests have been conducted for more than 1 month and, the strip performance with regard to precision and accuracy were within the acceptance criteria. The test for open vial strip lots is ongoing

Extended Open Vial Stability Evaluation
Strip performance assessment mimics the use of test strips from vials that have been left completely open when stored at different combinations of temperature and humidity spanning the recommended storage conditions. The purpose of extended open vial strip stability test is to determine the stability duration of test strips with the cap vial left off for an extended period of time. At every time points, precision evaluation is performed using control solutions and whole blood samples. Accuracy is also evaluated using spiked or glycolyzed whole blood samples to span the claimed measuring range, and the SMBG results be compared to values obtained with the comparator method.

Extended open vial stability test was conducted for 96 hours (4 days) at 5 combined temperature and humidity conditions. For the accuracy assessment, as the exposure time increased, the measurement results tended to result in higher measurement results. The measurement results started to go off the acceptance criteria starting from day 3 (72 hours) at 30℃ – 80% RH conditions. For the precision assessment as well, the closeness of data points started to broaden from day 3. Therefore, it is recommended that the strips that have been open in the air for more than 2 days should not be used especially at high temperature and humidity conditions.

Altitude Test
High altitude often involves extremes of temperature and humidity and can result in changes to hematocrit and blood pressure. The altitude effects study compares results from whole blood samples with the SMBG results at different high-altitude conditions relative to the comparator method. The studies also include a pressure change. Altitude pressure changes are accomplished by simulating increasing altitudes and atmospheric conditions in a pressurized chamber.

The altitude effects test was conducted at sea level (0 feet), at simulated altitudes of 5,000 feet and 10,000 feet. It was confirmed that CareSens S Fit SMBG test systems have no systematic response to altitudes and is not significantly affected by lack of atmospheric oxygen up to 10,000 feet (3,048 m) above the sea level.

Operating Condition Test
Measurements are made on whole blood samples under various operating temperature and humidity conditions. Tested temperature and humidity ranges not only cover the operating ranges specified in the device labeling, but

also the ranges outside of the claimed operating ranges. Meter measurement results are compared to values obtained with the reference method (YSI). Operating condition test was conducted using meters with altered firmware that shows numerical response at temperature conditions that would normally display “Er3” error messages outside of operating conditions. It is confirmed that CareSens S Fit SMBG test system operates normally at the claimed environmental conditions, compared to the YSI results.

Altitude Effects Evaluation

High altitude often involves extremes of temperature and humidity and can result in changes to hematocrit and blood pressure. The altitude effects study compares results from whole blood samples with the SMBG results at different high-altitude conditions relative to the comparator method. The studies also include a pressure change. Altitude pressure changes are accomplished by simulating increasing altitudes and atmospheric conditions in a pressurized chamber. It was confirmed that CareSens S Fit SMBG test systems have no systematic response to altitudes and is not significantly affected by lack of atmospheric oxygen up to 10,000 feet (3,048 m) above the sea level.

Flex Study (Strip Properties)

Flex studies are designed to test some of the factors that may contribute to erroneous results when used in home use settings rather than in professional healthcare settings. The robustness of the SMBG is also demonstrated through operating conditions test, altitude effects test, and stability tests. Other potential sources of errors are tested in this set of tests including Samples outside the Measuring Range, Short Sample Detection, Sample Perturbation Study, and Intermittent Sampling. In all of the tests, the meters correctly displayed Error messages when out of range measurements were taken, or did not affect the measurement results.

Cleaning and Disinfection Study

The device is intended for single patient home use. Disinfection studies were performed on the surface areas of 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 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 and the external materials of the meter and lancing device.

Data demonstrating substantial equivalence	The candidate device was tested in accordance with FDA Guidance for Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use. Analytical performance testing included method comparison, repeatability, and intermediate precision testing, etc. 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.

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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.