August 10, 2023

i-SENS, Inc.
H.S. Yoo
Regulatory Affairs Specialist /Manager
43, Banpo-Daero 28 Gil
Seocho-Gu, Seoul 06646
South Korea

Re: K230625
Trade/Device Name: ReliOn Premier BLU Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: July 12, 2023
Received: July 14, 2023

Dear H.S. Yoo:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joshua Balsam -S

Joshua M. Balsam, PhD.
Branch Chief
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230625

Device Name
ReliOn Premier BLU Blood Glucose Monitoring System

Indications for Use *(Describe)*
The ReliOn Premier BLU Blood Glucose Monitoring System is comprised of the ReliOn Premier BLU Blood Glucose Meter and the ReliOn Premier Blood Glucose Test Strips.

The ReliOn Premier BLU Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips.

The ReliOn Premier BLU 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.

The system is not intended for use on neonates and is not for the diagnosis or screening of diabetes.

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."

i-SENS, Inc.
43, Banpo-Daero 28-Gil, Seocho-Gu, Seoul, Korea, 06646
Tel.: +82-2-916-6191 | Fax.: +82-2-942-2514 | www.i-sens.com

k230625

510(k) Summary

Prepared in accordance with the requirements of 21 CFR 807.92 to provide an understanding of the basis for a substantial equivalence determination.

Date prepared: July 28, 2023

1. Applicant Information

Name	: i-SENS, Inc.
Address	: 43, Banpo-daero 28-gil, Seocho-gu, Seoul, South Korea 06646
Applicant Contact Correspondent	: H.S. Yoo (Regulatory Affairs Specialist / Manager) i-SENS, Inc., 43, Banpo-daero 28-gil, Seocho-gu, Seoul, South Korea 06646
E-mail	: registration@i-sens.com

2. Medical Device Information

Device Name	: ReliOn Premier BLU Blood Glucose Monitoring System
Common name	: Blood Glucose Monitoring System
Regulation number	: 21 CFR 862.1345
Class	: Class II
Product Code	: NBW
Submission Type	: Special 510(k)

3. Predicate Device Information

CareSens N Premier BT Blood Glucose Monitoring System (k170614)

4. Device Description

The ReliOn Premier BLU Blood Glucose Monitoring System is a blood glucose meter with Bluetooth Low Energy technology that the meter communicates to smartphones wirelessly. The ReliOn Premier BLU BGMS has a target range indicator that upon consulting with a healthcare professional, users have the option to activate the function that displays blood glucose measurement results on a colored backlight display. By default, this indicator function is set to OFF. However, it is recommended that users consult with a healthcare professional to determine the target range for their individual needs.

5. Intended Use

The ReliOn Premier BLU Blood Glucose Monitoring System is comprised of the ReliOn Premier BLU Blood Glucose Meter and the ReliOn Premier Blood Glucose Test Strips.

The ReliOn Premier BLU Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips.

The ReliOn Premier BLU 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.

The system is not intended for use on neonates and is not for the diagnosis or screening of diabetes.

6. Technological characteristics compared to the Predicate device

Feature	Predicate device CareSens N Premier BT (k170614)	Candidate device ReliOn Premier BLU Blood Glucose Monitoring System
Measurement range	20-600 mg/dL	Same
Sample size	Minimum 0.5 µL	Same
Test time	5 seconds	Same
Sample type	Fresh capillary whole blood	Same
Calibration	Plasma-equivalent	Same
Battery life	1,000 tests	Same
Power	Two 3.0V lithium batteries (disposable, type CR2032)	Same
Memory	1,000 test results	Same
Target range indicator	N/A	Red, Green, Blue colored screens for below, within, and above target range.

7. Modification from the predicate device

The modifications made are as follows:

a. The inclusion of a target range function with the red, green, and blue backlight screen.
b. Change in the LCD specifications, which consists of three backlight colors and the addition of C-Clips for connecting to the PCB.
c. Amendments to the PCB to enable connection of the LCD to other components of the blood glucose meter.
d. Updates to the labeling to feature information on the target range function and the method for setting the target range.

8. Performance Testing (Non-Clinical Testing)

The verification and validation activities carried out based on the adoption of the target range function included the following tests: Software function tests, power consumption, battery lifetime, memory, EMC, electrical safety, and human factors study.

The results of these tests indicated that the ReliOn Premier BLU Blood Glucose Monitoring System, with the proposed changes outlined in this document, performed as intended and fulfilled the specifications.

9. Conclusion

The verification and validation results demonstrated that the ReliOn Premier BLU Blood Glucose Monitoring System has been shown to be substantially equivalent to the predicate device, CareSens N Premier BT Blood Glucose Monitoring System (K170614).