DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 7, 2015

I-SENS, INC.
JOON JUNG
RA TEAM MANAGER
43, BANPO-DAERO 28-GIL, SEOCHO-GU
137-873 SEOUL KOREA

Re: K151164
Trade/Device Name: Assure Prism multi Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW
Dated: July 9, 2015
Received: July 10, 2015

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. 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,

Yung W. Chan -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)*
K151164

Device Name
Assure Prism multi Blood Glucose Monitoring System

Indications for Use *(Describe)*

The Assure® Prism multi 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 (forearm, palm, thigh, and calf). Alternative site testing should be used only during steady-state blood glucose conditions. The system is intended for use outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with auto-disabling, single use lancing device. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.

Assure® Prism multi Blood Glucose Test Strips are for use with the Assure® Prism multi blood glucose meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites.

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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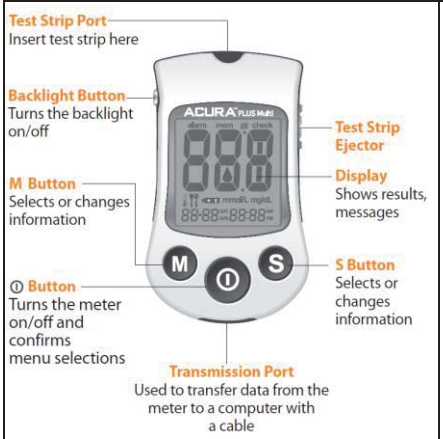
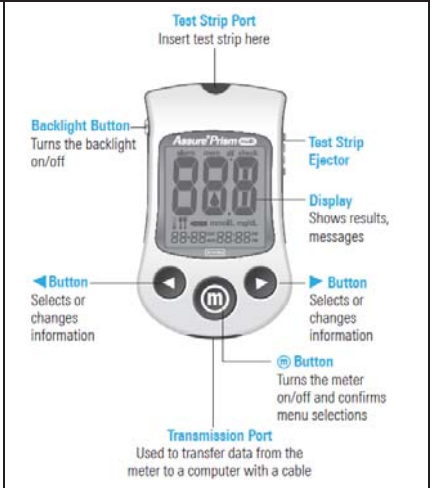
k151164

510(k) Summary

(As required by 21 CFR 807.92)

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)	**Special 510(k)**
Submitter Information	i-SENS, Inc. 43, Banpo-daero 28-gil, Seocho-gu 137-873, Seoul, Korea Tel.) +82-2-916-6191 Fax) +82-2-942-2514 e-mail: jhjung@i-sens.com Contact Person: Joon Ho Jung
Prepared Date	April, 29th, 2015
Device Name and Classification	Trade name: **Assure Prism multi Blood Glucose Monitoring System** Common name: Blood Glucose Test System Classification product code: NBW, CGA Regulation number: 21 CFR 862.1345 Glucose Test System Classification panel: 75, Chemistry Device class: Class II
Predicate Device Information	Device name: ACURA Plus Multi Blood Glucose Monitoring System 510(k) number: K131419
Device Description	The Assure Prism multi Blood Glucose Monitoring System (BGMS) consists of a multi use blood glucose meter, test strips, and control solutions with two different glucose concentrations ("Control A" and "Control B" ranges, sold separately). The Assure Prism multi BGMS are 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.
Intended Use:	The Assure Prism multi 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 (forearm, palm, thigh, and calf).

<table>
<tr><td></td><td>Alternative site testing should be used only during steady-state blood glucose conditions. The system is intended for use outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with auto-disabling, single use lancing device. It is not intended for use on neonates and is not for the diagnosis or screening diabetes.
Assure Prism multi Blood Glucose Test Strips are for use with the Assure Prism multi blood glucose meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternatives sites.</td></tr>
<tr><td>Comparison to the Predicate Device</td><td>The candidate device and the predicate device consist of the same meter and test strips. The measurement principle, fundamental scientific technology, operating ranges, and performance characteristics of the candidate device remain the same as those of the predicate device. Assure Prism multi has not changed since its CLIA categorization. Additional 3 disinfectants have been validated in order to be used with the system upon clearance. Accordingly, there have been some labeling changes made in accordance with the addition of the 3 disinfectants. The differences in appearance of meter and test strips are as follows.
<table>
<tr><th>Features</th><th>ACURA Plus Multi BGMS (Predicate device, k131419)</th><th>Assure Prism multi BGMS (Candidate device k151164/CR140257)</th></tr>
<tr><td>Meter shell</td><td colspan="2">Differences in meter button symbols (functions remain the same)</td></tr>
<tr><td></td><td> 
</td><td> 
</td></tr>
<tr><td>Test</td><td colspan="2">Differences in test strip logo (same in its chemical composition, dimension, manufacturing process, assay method, etc)</td></tr>
</table></td></tr>
</table>

	Strip Logo		
Type of Test	Quantitative, Amperometric method, Glucose oxidase *(Aspergillus sp.)*		
Test Principle	The reagent on the test strip produces a small electrical current using glucose as a substrate in the blood sample. The meter converts electrical current to glucose concentration.		
Summary of Pre-cleaning and Disinfection	The device is intended for multiple patients use in a professional healthcare setting. Disinfection study was performed on the meter by an outside commercial testing service to evaluate effectiveness of disinfectants, Dispatch® Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No: 56392-7), CaviWipes1 (EPA Reg. No: 46781-13), and PDI ®Super Sani-Cloth® Germicidal Disposable Wipe (EPA Reg. No: 9480-4) 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.		
	We have also demonstrated that 10,950 each of cleaning and disinfection cycles for meter with the same disinfectant designed to simulate 3 years of multiple-patient use has no effect on the performance or the external materials of the meter.		
Conclusion	**Based on the submitted information in this premarket notification, the candidate device is substantially equivalent to the predicate device. Further, the candidate device has met the performance, safety, and effectiveness of the device for its intended use.**		