DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 2, 2017

iXENSOR COMPANY LTD.
C/O FENG-YU LEE
IVDD REGULATORY CONSULTANT
29222 RANCHO VIEJO RD, SUITE 218
SAN JAN CAPISTRANO CA 92675

Re: K163087
Trade/Device Name: PixoTest Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW
Dated: October 25, 2017
Received: October 30, 2017

Dear Feng-Yu Lee:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k163087

Device Name
PixoTest Blood Glucose Monitoring System

Indications for Use *(Describe)*
The PixoTest Blood Glucose Monitoring System is comprised of PixoTest Glucose Test Strip, PixoTest Uni-Clip, and the PixoHealth App as the display component of the system.
The PixoTest Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip.
The PixoTest 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 for single person use only and should not be shared. It is not intended for use in the diagnosis of or screening for diabetes and is not intended for use on neonates.

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

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

The assigned 510(k) number is: k163087

1. Submitter Identification:

iXensor Co. Ltd.
6F, No. 9, Aly. 2, Ln.35, Jihu Rd., Neihu Dist., Taipei City 114, Taiwan

c/o IVDD Regulatory Consultant
Contact Person: Mrs. Feng-Yu Lee
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Date Summary Prepared: October 25, 2017

2. Name of the Device:

PixoTest Blood Glucose Monitoring System

3. Common or Usual Name: Blood Glucose Monitoring System

Product Code	Classification	Regulation Section	Panel
NBW; System, Test, Blood Glucose, Over-the-Counter	Class II	21 CFR 862.1345	Clinical Chemistry 75

4. Device Description:

PixoTest BGMS consists of the following devices:

1) PixoTest Glucose Test Strip (single-use) – *abbreviated as Glucose Test Strip*
2) PixoTest Control Solutions (2 levels – 1 and 2) – *optional*
3) PixoTest Standard Card
4) PixoTest Uni-Clip
5) PixoHealth App
6) Requires compatible smartphone (iPhone 5/5S/6/6S) – *not provided by iXensor*

iXensor provides the following kits:

1) **Starter (5 Pcs) Kit**– includes PixoTest Standard Card, PixoTest Uni-Clip, and 5 Pcs Glucose Test Strip

2) **10 Pcs Kit** – includes PixoTest Standard Card and 10 Pcs PixoTest Glucose Test Strip

The PixoTest BGMS uses glucose oxidase test methodology to measure capillary whole blood glucose levels from 40 to 500 mg/dL. The system will display “Hi” when the results are above 500 mg/dL and “Lo” when the results are below 40mg/dL.

Expected glucose values without diabetes*

Blood Glucose Normal Range	
Status	**Glucose Level**
Fasting for 8 Hours	Less than 100 mg/dL
Oral Glucose Tolerance Test	Less than 140 mg/dL

* Diagnosing Diabetes and Learning About Prediabetes- American Diabetes Association (ADA) [Electronic Version] Retrieved Apr. 27, 2017 from www.diabetes.org/diabetes-basics/diagnosis/

5. Intended Use:

The PixoTest Blood Glucose Monitoring System is comprised of PixoTest Glucose Test Strip, PixoTest Uni-Clip, and the PixoHealth App as the display component of the system. The PixoTest Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip. The PixoTest Blood Glucose Monitoring System is intended for self-testing outside of 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 for single person use only and should not be shared. It is not intended for use in the diagnosis of or screening for diabetes and is not intended for use on neonates.

6. Predicate Device Information

PixoTest BGMS is substantially equivalent to the following device:

BGMS

Name: Accu-Chek Active System
Device Company: Roche Diagnostics Corporation
510(K) Number: K021827

7. Comparison to Predicate Devices:

Specification	Subject Device – PixoTest BGMS		Predicate Device – Roche Accu-Chek Active System
	for iPhone 5/5S	for iPhone 6/6S	
Similarities & Differences			
Indications for Use	Over-The-Counter: For single-patient use only, in-vitro diagnostic use only by individuals with diabetes at home		OTC: For single-patient use only, in-vitro diagnostic use only by individuals with diabetes at home; and Professional: For multiple-patient use by health care professional in clinical setting
Test Principle	Reflectance photometry		
Sample Type	Capillary whole blood		
Sample Volume	1.8 µL		1-2 µL
Primary Site Testing	Fingertip		

Alternative Site Testing	N/A		Forearm, calf, thigh, upper arm, palm
Unit of Measurement	mg/dL		
Measuring Range	40-500 mg/dL		10-600 mg/dL
Measuring Time	8 seconds		5 seconds
Hematocrit	20-60%		30-55%
Maximum Altitude	9,843 ft. (3000 m)		13,123 ft. (4000 m)
Test Strip Operating Temperature	50-95°F (10-35°C)		5-104°F (10-40°C)
Test Strip Operating Humidity	10-90% relative humidity		< 85% relative humidity
Test Strip Shelf-Life	24 months		18 months
Test Strip Storage Temperature	50-104°F (10-40°C)		36-86°F (2-30°C)
Test Strip Reagent	Glucose Oxidase		Glucose Dehydrogenase
Interference Substances	Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin C), and other reducing substances		Ascorbic acid, Galactose, Bilirubin, Ceftriaxone
Compatible Device/OS	iPhone 5/5S/6/6S; iOS 8 or above		N/A, Meter
Device Dimension	iPhone 5/5S: 4.87 x 2.31 x 0.3 in. (123.8 x 58.6 x 7.6 mm)	iPhone 6/6S: 5.44 x 2.64 x 0.28 in. (138.3 x 67.1 x 7.1 mm)	Meter: 4.1 x 2 x 0.9 in. (104.5 x 51.5 x 22 mm)
Device Weight	iPhone 5/5S: 112g	iPhone 6/6S: 143f	Meter: 55g without battery 60g with battery
Device Storage Temperature	N/A		Meter: -40-158°F (-40-70°C)
Power Supply	iPhone 5/5S6/6S: Built-in rechargeable lithium-ion battery		Meter: 1 type CR 2032 or equivalent lithium battery
Battery Life	N/A		1000 tests
Device Display	LCD		
Display Area	iPhone 5/5S: 4 in.	iPhone 6/6S: 4.7 in.	Meter: 2 in.
Memory Capacity	1000 blood glucose test results with date and time		200 blood glucose test results with date and time
Coding Procedure	Code Key		
Voice Function	No		

Statement of No Differences:
For the reasons mentioned above, it can be concluded that the PixoTest BGMS are substantially equivalent to the Roche Accu-Chek Active System in commercial distribution, with respect to indications for use and technology.

8. Technology Characteristics:

PixoTest BGMS is a device that utilizes smartphone technology in conjunction with reflectance photometry and glucose-oxidase chemical reaction testing principles to measure the glucose level in human blood. A small drop of blood (minimum 1.8 microliter) is applied to the eyelet on top of the disposable *PixoTest Glucose* test strip with integrated lancet cartridge. The blood sample is then transferred to and absorbed by the test strip's glucose-oxidase impregnated reagent pad, which reacts with the glucose to produce a color change. The intensity of the color change is proportional to the glucose concentration present in the blood sample. After 8 seconds, the blood glucose measurement result is displayed on the smartphone screen via *PixoHealth* App.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Verification and validation tests were performed to evaluate the performance, functionality, and reliability of the PixoTest BGMS. The evaluations include precision, linearity and sensitivity, interference, sample volume, and hematocrit.

10. Discussion of Clinical Tests Performed:

System Accuracy (iPhone 5/5S):
A system accuracy study of the *PixoTest* BGMS was performed by comparing capillary whole blood glucose values on the *PixoTest* BGMS with values on YSI 2300 Analyzer lab instrument.

The evaluation was conducted on 100 different subjects using 2 *PixoTest* BGMS including compatible smartphone (iPhone 5S with PixoHealth App), taking duplicate measurements from 3 test strip reagent lots.

The study results demonstrate that the accuracy specifications of *PixoTest* BGMS meet the acceptance criteria.

System Accuracy (iPhone 6/6S):
A system accuracy study of the *PixoTest* BGMS was performed by comparing capillary whole blood glucose values on the *PixoTest* BGMS with values on YSI 2300 Analyzer lab instrument.

The evaluation was conducted on 100 different subjects using 2 *PixoTest* BGMS including compatible smartphone (iPhone 6S with PixoHealth App), taking duplicate measurements from 3 test strip reagent lots (6 measurements total per subject).

The study results demonstrate that the accuracy specifications of *PixoTest* BGMS meet the acceptance criteria.

Usability/User Performance (iPhone 5/5S):
A user performance study was performed to demonstrate the following:
1) User Accuracy – lay users can obtain accurate results while using PixoTest BGMS
2) Usability – English speaking and reading lay users find PixoTest BGMS system easy to use and user manual is easily understandable across all educational backgrounds.

The evaluation was conducted on 105 subject first time users with 3 lots of *PixoTest* BGMS including compatible smartphones (iPhone 5S with Pixo Health App), all accessories, and accompanying documents

The study results demonstrate that the usability (via questionnaire), user accuracy, and risk assessment specifications of PixoTest BGMS meet the acceptance criteria.

Usability/User Performance (iPhone 6/6S):

A user performance study was performed to demonstrate the following:

3) User Accuracy – lay users can obtain accurate results while using PixoTest BGMS
4) Usability – English speaking and reading lay users find PixoTest BGMS system easy to use and user manual is easily understandable across all educational backgrounds.

The evaluation was conducted on 105 subject first time users with 3 lots of *PixoTest* BGMS including compatible smartphones (iPhone 6S with PixoHealth App), all accessories, and accompanying documents.

The study results demonstrate that the usability (via questionnaire), user accuracy, and risk assessment specifications of PixoTest BGMS meet the acceptance criteria.

11. Conclusions:

Performance evaluations of the PixoTest BGMS demonstrate substantial equivalence to the predicate device, Roche Accu-Chek Active System.