November 19, 2024

TaiDoc Technology Corporation
Jacky Chou
Vice President
B1-7F, No.127, Wugong 2nd Rd., Wugu District
New Taipei City, 24888
Taiwan

Re: K221349
Trade/Device Name: XPER Technology PREMIUM Pro Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: PZI
Dated: March 11, 2024
Received: March 11, 2024

Dear Jacky Chou:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K221349

Device Name
XPER Technology PREMIUM Pro Blood Glucose Monitoring System

Indications for Use *(Describe)*
The XPER Technology PREMIUM Pro Blood Glucose Monitoring System consists of the XPER Technology PREMIUM Pro Blood Glucose Meter and XPER Technology PREMIUM Pro Blood Glucose Test Strips.
The XPER Technology PREMIUM Pro Blood Glucose Monitoring System is intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of glucose in fresh capillary whole blood samples from the fingertips in endocrinology clinic laboratories and physician office laboratories.
The system should only be used with single-use, auto-disabling lancing devices when performing a fresh capillary whole blood sample from the fingertip.
The system is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.
The system is not intended for use on patients receiving intensive medical intervention/therapy.
The system is not intended for use in acute care, nursing facilities, skilled nursing facilities or hospital settings.
The system 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.

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.

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"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."

510(k) Summary

In accordance with the requirements of 21 CFR 807.92, this summary is being provided to serve as the basis for the substantial equivalence determination.

Submitter Information

Manufacturer	TaiDoc Technology Corporation
Address	B1-7F, No.127, Wugong 2nd Rd., Wugu District, New Taipei City, Taiwan 24888
Establishment Registration No.	3004145393
Date Prepared	November 18, 2024
Correspondent	TaiDoc Technology Corporation
Correspondent Contact	Jacky Chou
Title	Vice President
Phone Number	+886-2-6625-8188
Fax Number	+886-2-6625-0868
E-mail	jacky.chou@taidoc.com.tw

Candidate Device Information

Proprietary Name	XPER Technology PREMIUM Pro Blood Glucose Monitoring System
Common Name	Glucose Test System
510(k) Number	K221349
Product Code	PZI, Prescription Use Blood Glucose Meter For Near-Patient Testing
Classification panel	Clinical Chemistry
Classification	2
Regulation Number	21 CFR §862.1345

Predicate Device Information

Manufacturer	Arkray, Inc.
Proprietary Name	Assure® Titanium Blood Glucose Monitoring System
Common Name	Glucose Test System
510(k) Number	K200788

Indications for Use

The XPER Technology PREMIUM Pro Blood Glucose Monitoring System consists of the XPER Technology PREMIUM Pro Blood Glucose Meter and XPER Technology PREMIUM Pro Blood Glucose Test Strips.

The XPER Technology PREMIUM Pro Blood Glucose Monitoring System is intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of glucose in fresh capillary whole blood samples from the fingertips in endocrinology clinic laboratories and physician office laboratories.

The system should only be used with single-use, auto-disabling lancing devices when performing a fresh capillary whole blood sample from the fingertip.

The system is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.

The system is not intended for use on patients receiving intensive medical intervention/therapy.

The system is not intended for use in acute care, nursing facilities, skilled nursing facilities or hospital settings.

The system is not intended for use on neonates.

Device Description

The XPER Technology PREMIUM Pro Blood Glucose Monitoring System consists of the XPER Technology PREMIUM Pro Blood Glucose Meter, the XPER Technology PREMIUM Pro Blood Glucose Test Strips, and the TaiDoc Blood Glucose Control Solutions. This system is a multiple-patient use for the quantitative determination of glucose in capillary whole blood samples from the fingertips in endocrinology clinic laboratories and physician office laboratories as an aid in monitoring the effectiveness of glucose control. The TaiDoc Blood Glucose Control Solutions are used to check that the meter and test strips are working together properly.

Test Principle

The XPER Technology PREMIUM Pro Blood Glucose Monitoring System is designed to quantitatively measure the amount of blood sugar (glucose) in fresh capillary whole blood from fingertips. The glucose measurement is achieved by using the amperometric detection method that uses flavin adenine dinucleotide-dependent glucose dehydrogenase enzyme (FAD-GDH) based chemistry. Once a drop of blood sample is applied to the test strip, the blood sample is pulled into the test strip by capillary action. The glucose in the sample reacts chemically with the enzyme, generating electrons and producing an electric current that is proportional to the concentration of glucose in the sample. After the reaction time, the meter calculates and then displays the glucose concentration on LCD. The XPER Technology PREMIUM Pro Blood Glucose Monitoring System reports the glucose results in plasma equivalents.

Summary of Technological Characteristics and Comparison to the Predicate Device

The XPER Technology PREMIUM Pro Blood Glucose Monitoring System is substantially equivalent to the predicate device in terms of technological characteristics and similar in intended use.
The similarities and differences between the predicate and candidate devices are summarized in Table 1 and Table 2.

Table 1. Similarities between the Predicate and Candidate Device

Characteristic	Predicate Device K200788	Candidate Device K221349
	Assure® Titanium Blood Glucose Monitoring System	**XPER Technology PREMIUM Pro Blood Glucose Monitoring System**
Operation principle	Electrochemical biosensor technology	Identical
Detection method	Amperometric glucose enzyme	Identical
Sample type	Fresh capillary whole blood	Identical
Calibration	Automatic, no Calibration Code	Identical
Sample Size	0.5 µL	Identical
Hematocrit Range	10-70%	Identical
Handheld	Yes	Identical
User interface	Screen and buttons	Identical
Memory capacity	1000 measurements	Identical
Power source	2 AAA Batteries	Identical

Table 2. Differences between the Predicate and Candidate Device

Characteristic	Predicate Device K200788	Candidate Device K221349
	Assure® Titanium Blood Glucose Monitoring System	**XPER Technology PREMIUM Pro Blood Glucose Monitoring System**
Indications for Use	The Assure Titanium Blood Glucose Monitoring System consists of the Assure Titanium Blood Glucose meter and the Assure Titanium Blood Glucose test strips. The Assure Titanium Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The system is intended for in vitro diagnostic, point of care use in endocrinology clinics and nursing or skilled nursing facilities, for multiple patient use. This system should only be used with single-use, auto-disabling lancing devices for drawing finger stick capillary blood. The system is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia. The system is not intended for use in acute care or hospital settings. The system is not intended for neonatal use. The system is for prescription use only.	The XPER Technology PREMIUM Pro Blood Glucose Monitoring System consists of the XPER Technology PREMIUM Pro Blood Glucose Meter and XPER Technology PREMIUM Pro Blood Glucose Test Strips. The XPER Technology PREMIUM Pro Blood Glucose Monitoring System is intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of glucose in fresh capillary whole blood samples from the fingertips in endocrinology clinic laboratories and physician office laboratories. The system should only be used with single-use, auto-disabling lancing devices when performing a fresh capillary whole blood sample from the fingertip. The system is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.

Characteristic	Predicate Device K200788	Candidate Device K221349
	Assure® Titanium Blood Glucose Monitoring System	**XPER Technology PREMIUM Pro Blood Glucose Monitoring System**
		The system is not intended for use on patients receiving intensive medical intervention/therapy. The system is not intended for use in acute care, nursing facilities, skilled nursing facilities or hospital settings. The system is not intended for use on neonates.
Population Limitations	Not intended for neonatal use, acute care or hospital settings, nor for use with patients receiving intensive medical intervention/therapy.	Not intended for use neonatal use, acute care, nursing facilities, skilled nursing facilities, hospital settings, nor for use with patients receiving intensive medical intervention/therapy.
Wireless Data Communication	None	Bluetooth Low Energy (BLE)
Enzyme	Glucose oxidase (*Aspergillus niger* sourced)	FAD-Glucose dehydrogenase (*E. coli*)
Meter Size	4.7 x 2.4 x 1.2 inch	102.5(L) x 59.6(W) x 21.8(H) mm
Meter Weight	4.1 oz with batteries	64.4 g (without batteries)
Measuring Range	10-600 mg/dL	10-800 mg/dL
Time to Result	7 seconds	5 seconds
Operating temperature	46° to 104°F (8° to 40°C)	46.4° to 113°F (8° to 45°C)

Summary of Testing

Non-clinical and clinical studies were conducted to test, verify and validate the performance of the candidate device according to FDA Guidance issued on September 29, 2020: *Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use*. Results from these studies show that the device performance is substantially equivalent.

Non-Clinical Testing Summary:

Precision

Within-run and intermediate precision were performed to evaluate imprecision of the candidate device across the glucose measuring range (10-800 mg/dL).

The intermediate precision test was conducted for 10 days and 7 levels of control solutions and 3 lots of test strips were tested. 10 meters were tested for each day and each meter produced one measurement per day for one test strip lot and one level. Total 2100 measurements were obtained by meters for 3 lots of test strip in the end of test.

In within-run precision test, 7 levels of venous blood samples and 3 lots of test strips were tested. The venous blood samples were added to concentrated glucose solutions to achieve the glucose concentration ranges of 7 levels. The within-run precision test was conducted in 1 day, and 10 meters were tested and 10 measurements were produced per meter. Total 2100 measurements were obtained by meters for 3 lots of test strip in the end of test.

The precision data demonstrates that all test results were within acceptance criteria.

Linearity

The linearity was performed in accordance with CLSI Document EP6-A" *Evaluation of the Linearity of Quantitative Measurement: A Statistical Approach; An Approved Guideline*."

11 blood glucose levels were evaluated and the target glucose concentrations were verified by the YSI-2300 reference analyzer. The 5 meters worked with 3 test strip lots were tested. The linearity

data analysis showed that all test results were within acceptance criteria, which demonstrate the linearity of candidate device across the claimed measuring range 10-800 mg/dL.
3 test strip lots and 5 meters were tested with venous blood samples at glucose levels above and below the claimed measuring range. All meters met the acceptance criteria to display “Lo” at glucose levels < 10 mg/dL and to display "Hi" at glucose levels >800 mg/dL.

Hematocrit
The 13 levels of hematocrit were evaluated on the candidate device across the claimed hematocrit range 10% - 70%. The bias against YSI-2300 and the average of blood glucose value on 42% hematocrit were calculated to assess the hematocrit effect. All test results were within acceptance criteria, which demonstrate the claimed hematocrit range 10% - 70% doesn’t affect the performance of candidate device.

Interference
The effect of 58 endogenous and exogenous substances that are expected in the intended use environment were evaluated on the candidate device. The 3 target blood glucose ranges were tested, and the bias against the YSI-2300 was calculated to assess the interfering effect for each substance.
For each concentration of potential interfering substances, average percent bias to untreated control samples and 95% confidence intervals were calculated. The interference data showed the highest concentration with no interference and the maximum test concentration of each interfering substances tested. According to the interference data, Xylose in the blood can give falsely elevated results, and Pralidoxime Iodide level to > 5 mg/dL may affect the glucose results.

Disinfection validation test
The disinfection validation test was performed by Microbac Laboratories.
The duck hepatitis B virus was used to evaluate the efficacy of Clorox Healthcare ™ Bleach Germicidal Wipe (EPA No.: 67619-12) on candidate device. The reduction of virus was within acceptance criteria, and the complete inactivation of virus were achieved, which demonstrate the Clorox Healthcare ™ Bleach Germicidal Wipe (EPA No.: 67619-12) can effectively eliminate duck hepatitis B virus from the surface of candidate device.

Robustness test
Robustness were performed to demonstrate that the candidate device can withstand multiple cleaning and disinfection cycles within 5 years of shelf life.
The number of cleaning and disinfection cycles performed for this testing was based 15 cleaning and disinfection cycles per day for 5 years for a total of 27,500 cycles (15 cycles per day x 365 days per year x 5 years = 27,375 cycles of cleaning and disinfection). The Clorox Healthcare ™ Bleach Germicidal Wipe (EPA No.: 67619-12) was used in this test, and the performance and physical inspection are performed at start (0 cycle), middle (13,750 cycles) and end point (27,500 cycles). All test results are within acceptance criteria, which demonstrates that the candidate device maintains its intended use under 27,500 cycles of cleaning and disinfection by using Clorox Healthcare ™ Bleach Germicidal Wipe.

Flex studies
The following flex studies were performed to confirm the fail-safe mechanisms of candidate device is effective under stress conditions. All test results were within acceptance criteria, which demonstrate the risks of imprecisions are effectively mitigated under normal use.
- Drop and vibration
- Sample Perturbation Study Procedure
- Intermittent Sampling
- Blood Volume Test
- Used Test Strips
- Error Codes for Samples Outside the Measuring Range
- Clotted samples

- Incorrect Test Strips
- Test Strips Removal Verification
- Altitude

Stability

The test strip vial stability is evaluated using open vial and close vial real time stability. The protocols and acceptance criteria are reviewed and found acceptable to support the labeling claims that the test strips are stable after first being opened, and that closed vials are stable for 12 months at the recommended storage temperature 35.6-86°F (2-30°C) and 10-90% relative humidity.

Clinical study summary:

A clinical study was conducted at 3 U.S. sites with 10 operators and 6 Taiwan sites with 18 operators that had environments and operators representative of endocrinology clinic laboratories and physician office laboratories.

The capillary blood samples from 414 patients were measured and the results were compared to the YSI Model 2300 Glucose Analyzer.

The Table 3 and Table 4 show differences in glucose values between the candidate device and the YSI method.

Table 3. Overall accuracy for blood glucose concentrations < 75 mg/dL.

Difference range between the true blood glucose level and the candidate device results.	Within ±5 mg/dL	Within ±10 mg/dL	Within ±12 mg/dL	Within ±15 mg/dL	Exceeds ±15 mg/dL
The percentage (numbers) of samples for which the difference between the candidate device and the YSI-2300 were within the difference range shown in the top row.	8/13 (61.5%)	12/13 (92.3%)	13/13 (100%)	13/13 (100%)	0/13 (0%)

Table 4. Overall accuracy for blood glucose concentrations ≧75 mg/dL

Difference range between the true blood glucose level and the candidate device results.	Within ±5 %	Within ±10 %	Within ±12 %	Within ±15 %	Within ±20 %	Exceeds ±20 %
The percentage (numbers) of samples for which the difference between the candidate device and the YSI-2300 were within the difference range shown in the top row.	224/401 (55.9%)	356/401 (88.8%)	391/401 (97.5%)	399/401 (99.5%)	401/401 (100%)	0/401 (0%)

Extreme blood glucose value

The accuracy at extremes blood glucose was performed in the extreme upper (>300 mg/dL) and lower blood glucose range (<80 mg/dL).

Blood samples were collected and allowed to glycolyze or were spiked with high concentration glucose solution to acquire 100 samples for testing with the candidate device, and the candidate device results were compared to the YSI-2300. There were 50 samples with glucose <80 mg/dL and 50 with glucose >300 mg/dL.

Medications and Medical Conditions

The subjects in clinical studies can represent the intended use setting. The medical conditions and medications at 9 clinical locations are identified.

During the clinical study, participants received approximately 69 medications representing over 17 parent drug classes and over 17 drug subclasses (with as many as 4 different drugs administered to each patient).

According to the medications and medical conditions of subjects from 3 U.S. sites and 6 Taiwan sites, all participants have conditions and are taking medications that are similar to the common patient medications and conditions who needs to measure blood glucose values in the U.S physician offices and endocrinology clinics. The medications and medical conditions of participants in clinical study can represent the indications for use environment.

Usability

A usability was conducted during the clinical study to evaluate the ease of use/understanding of the candidate device. The Owner's Manual, Quick Reference Instructions and Quick Reference Instructions (for Bluetooth pairing) were provided in the clinical study, and operators filled out the questionnaire at the end of study. The results demonstrated that the candidate device is easy to use, and the labeling is easy to understand.

Conclusion

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device. Based on the information provided in this submission, the XPER Technology PREMIUM Pro Blood Glucose Monitoring System has been shown to be substantially equivalent to the predicate device.