



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT**

I Background Information:

A 510(k) Number

K221349

B Applicant

TaiDoc Technology Corporation

C Proprietary and Established Names

XPÉR Technology PREMIUM Pro Blood Glucose Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PZI	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device intended for endocrinology clinic laboratories and physician office laboratories. The sponsor chose not to seek CLIA Waiver by application for this device.

B Measurand:

Glucose in fresh capillary whole blood samples from the fingertips.

C Type of Test:

Quantitative amperometric assay (glucose dehydrogenase-FAD)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

- For in vitro diagnostic use (for use outside of the body only).
- This test is not CLIA Waived and should not be used in CLIA Waived environments.
- Not for patients undergoing tight glycemic control.
- Not for the screening or diagnosis of diabetes mellitus.
- Not for use on patients receiving intensive medical intervention/therapy.
- Not for use in acute care, nursing facilities, skilled nursing facilities or hospital settings.
- The system is not for pediatrics under 18 years old.
- Do not use to test neonates. The XPER Technology PREMIUM Pro Blood Glucose Monitoring System has not been validated for neonatal use.
- Severe dehydration and excessive water loss may cause readings which are lower than actual values.
- The device should not be used on severely hypotensive individuals.
- This system should not be used in patients receiving intensive medical intervention/therapy because of the potential for preanalytical collection error and specifically in patients with decreased peripheral blood flow, as it may not reflect the true physiological state when test

results are generated using capillary whole blood samples. Examples include, but are not limited to, severe hypotension, coma, shock, hyperosmolar-hyperglycemia (with or without ketosis), impaired peripheral circulation, and severe dehydration.

- The system should only be used with single-use, auto-disabling lancing devices when performing a fresh capillary whole blood sample from the fingertip.
- Altitudes above 15,000 feet (4,500 m) may affect the test results.
- Not for Alternative Site Testing (AST).

D Special Instrument Requirements:

XPER Technology PREMIUM Pro Blood Glucose Meter

IV Device/System Characteristics:

A Device Description:

The XPER Technology PREMIUM Pro Blood Glucose Monitoring System consists of the handheld XPER Technology PREMIUM Pro Blood Glucose Meter and the XPER Technology PREMIUM Pro Blood Glucose Test Strips. The TaiDoc Blood Glucose Control Solutions (Levels Y1, W2, B3) are sold separately.

B Principle of Operation:

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 blood sample is pulled into the test strip by capillary action. The glucose measurement is based on the amperometry achieved with the glucose dehydrogenase enzyme (GDH) and flavin adenine dinucleotide (FAD)-dependent based chemistry. The glucose in the sample reacts with GDH to produce electrons that are transferred to the electrodes via FAD and a mediator. The resulting electric current is proportional to the concentration of glucose in the sample. After the reaction the meter calculates the detected current and reports the glucose concentration in plasma equivalents.

C Instrument Description Information:

1. Instrument Name:

XPER Technology PREMIUM Pro Blood Glucose Meter

2. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

3. Specimen Sampling and Handling:

The glucose test is intended to be used with capillary fingerstick whole blood. The blood sample is applied directly to the test strip by capillary action.

4. Calibration:

The meter does not require calibration or coding by the user. The detection of the calibration code is automatic.

5. Quality Control:

Three levels of TaiDoc Blood Glucose Control Solutions (Y1, W2, B3) are available for use with the XPER Technology PREMIUM Pro Blood Glucose Monitoring System. Instructions on how to order control solutions, and when to perform a control solution test are included in the labeling. The acceptable range for each control level is printed on the test strip bottle or on the bottom of the test strip box. The meter automatically recognizes and flags the test result in the memory as a control solution test result. The user is cautioned not to use the meter and to contact the customer support if the control result falls outside the ranges printed on the test strip vial label.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Assure Titanium Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

K200788

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K221349</u>	<u>K200788</u>
Device Trade Name	XPER Technology PREMIUM Pro Blood Glucose Monitoring System	Assure Titanium Blood Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use	The XPER Technology PREMIUM Pro Blood Glucose Monitoring System is intended for point-of-care,	Same

	<i>in vitro</i> diagnostic, multiple-patient use for the quantitative determination of glucose for use in determining dysglycemia.	
Test Principle	Electrochemical biosensor technology (amperometric)	Same
Sample Type	Capillary whole blood (fingertip),	Same
Sample Volume	0.5 µL	Same
Hematocrit range	10 to 70%	Same
General Device Characteristic Differences		
Enzyme	Glucose dehydrogenase-FAD	Glucose oxidase
Environments	Endocrinology clinical laboratories, Physician office laboratories	Endocrinology clinics, Nursing or Skilled-nursing facilities
Measuring Time	5 seconds	7 seconds
Measuring range	10 to 800 mg/dL	10 to 600 mg/dL
Data Transmission	Bluetooth	None

VI Standards/Guidance Documents Referenced:

ISO 14971 Third Edition 2019-12, Medical devices - Application of risk management to medical devices.

CLSI EP05-A3 3rd Edition, Evaluation of Precision of Quantitative Measurement Procedures.

CLSI EP07 3rd Edition, Interference Testing in Clinical Chemistry.

FDA Guidance Document: Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use. Guidance for Industry and Food and Drug Administration Staff. Issued on September 29, 2020

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Within-run and intermediate precision for the XPER Technology PREMIUM Pro Blood Glucose Monitoring System were evaluated to assess imprecision of the system across the glucose measuring range.

Within-run precision was evaluated using venous whole blood spiked with high concentration glucose solution or allowed to glycolyze to seven glucose concentrations (10 to 30, 31 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400, and 600 to 800 mg/dL). Each level was tested with three lots of test strips in replicates of ten on each of ten meters, for a total of 100 measurements per lot and 300 per sample. Results for the within-run precision testing are summarized in the table below.

Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	%CV
10 to 30	1	100	25.50	0.522	2.05%
	2	100	25.56	0.538	2.10%
	3	100	25.48	0.522	2.05%
	Combined	300	25.51	0.527	2.06%
31 to 50	1	100	46.85	0.833	1.78%
	2	100	46.88	0.795	1.70%
	3	100	46.89	0.827	1.76%
	Combined	300	46.87	0.816	1.74%
51 to 110	1	100	102.13	1.796	1.76%
	2	100	102.27	1.406	1.37%
	3	100	102.07	1.610	1.58%
	Combined	300	102.16	1.609	1.57%
111 to 150	1	100	138.01	2.130	1.54%
	2	100	138.00	2.089	1.51%
	3	100	137.77	2.131	1.55%
	Combined	300	137.93	2.113	1.53%
151 to 250	1	100	232.42	3.331	1.43%
	2	100	232.86	3.438	1.48%
	3	100	232.49	3.295	1.42%
	Combined	300	232.59	3.350	1.44%
251 to 400	1	100	378.64	5.310	1.40%
	2	100	377.84	5.425	1.44%
	3	100	379.03	5.347	1.41%
	Combined	300	378.50	5.366	1.42%
600 to 800	1	100	773.33	11.961	1.55%
	2	100	769.88	11.839	1.54%

Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	%CV
	3	100	770.38	12.204	1.58%
	Combined	300	771.20	12.059	1.56%

Intermediate precision was evaluated using seven control solutions at glucose levels within the ranges of 10 to 30, 31 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400, and 600 to 800 mg/dL. Each level was tested with three lots of test strips in replicates of ten on each of ten meters over ten days with multiple operators, for a total of 210 results per glucose concentration and 2100 results total. Results for intermediate precision testing are summarized in the table below:

Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	%CV
10 to 30	1	100	27.19	0.486	1.79%
	2	100	27.26	0.485	1.78%
	3	100	27.25	0.557	2.05%
	Combined	300	27.23	0.510	1.87%
31 to 50	1	100	45.85	0.809	1.76%
	2	100	45.81	0.775	1.69%
	3	100	46.02	0.804	1.75%
	Combined	300	45.89	0.798	1.74%
51 to 110	1	100	97.04	1.456	1.50%
	2	100	97.27	1.517	1.56%
	3	100	97.16	1.562	1.61%
	Combined	300	97.16	1.510	1.55%
111 to 150	1	100	136.37	2.219	1.63%
	2	100	136.46	2.459	1.80%
	3	100	136.01	2.556	1.88%
	Combined	300	136.28	2.415	1.77%
151 to 250	1	100	221.52	3.433	1.55%
	2	100	220.87	3.460	1.57%
	3	100	221.71	3.462	1.56%
	Combined	300	221.37	3.459	1.56%
251 to 400	1	100	316.64	5.266	1.66%
	2	100	317.61	5.698	1.79%

Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	%CV
	3	100	316.39	5.101	1.61%
	Combined	300	316.88	5.369	1.69%
600 to 800	1	100	749.00	12.141	1.62%
	2	100	750.86	11.156	1.49%
	3	100	747.19	11.439	1.53%
	Combined	300	749.02	11.644	1.55%

2. Linearity:

Linearity of the XPER Technology PREMIUM Pro Blood Glucose Monitoring System was evaluated using venous whole blood spiked with high concentration glucose solution or allowed to glycolyze to achieve 11 glucose concentrations (9, 49, 78, 101, 137, 189, 287, 394, 588, 737 and 888 mg/dL). The target glucose concentrations were verified by the comparator method (YSI 2300 analyzer). Results on the candidate device were compared to results on the comparator. Each glucose level was tested using three test strip lots and five meters, for a total of 15 replicates per level and a total of 165 results.

The results are summarized below:

Test Strip Lot #	Slope	y-intercept	R ² -value
Lot 1	1.0098	1.5666	0.9991
Lot 2	1.0128	0.6173	0.9992
Lot 3	1.0112	1.0187	0.9988
Combined	1.0113	1.0675	0.9991

The results of the study support linearity of the XPER Technology PREMIUM Pro Blood Glucose Monitoring System across the claimed measuring range of 10 to 800 mg/dL. If the concentration of a sample is less than 10 mg/dL glucose, the result is flagged by the meter as “Lo”. If a sample exceeds 800 mg/dL glucose, the result is flagged by the meter as “Hi”. The “Lo” and “Hi” functions were validated and demonstrated to function as intended.

3. Analytical Specificity/Interference:

Interference testing was conducted to evaluate the effect of common endogenous substances and exogenous substances expected in the intended use population on the XPER Technology PREMIUM Pro Blood Glucose Monitoring System. Additional potential interferents were included in the testing following a detailed analysis of medications and medical conditions of the subjects evaluated in the method comparison study (see Section VII.C.3 below). The study was conducted by spiking 58 exogenous and endogenous substances into venous whole blood adjusted to three glucose levels (50 to 70, 110 to 130, and 225 to 270 mg/dL; as measured by the laboratory comparator method). Each of these samples was divided into a test pool and a control pool, with the potential endogenous and exogenous interfering

substances added to the test pool. The % bias was calculated from the difference between the test sample and the control sample using the mean of replicates for each of the 3 strip lots tested. The highest tested concentration for each substance at which no significant interference was observed (defined by the sponsor as a bias for the test sample within 10% of the control mean) is summarized in the following table:

Test Substance	Highest concentration tested with no significant interference
Acetaminophen	20 mg/dL
Ascorbic acid	5 mg/dL
Conjugated Bilirubin	50 mg/dL
Unconjugated Bilirubin	40 mg/dL
Cholesterol	500 mg/dL
Creatinine	30 mg/dL
Dopamine	20 mg/dL
EDTA	180 mg/dL
Galactose	1000 mg/dL
Gentisic acid	700 mg/dL
Pralidoxime Iodide	5 mg/dL
Reduced Glutathione	92 mg/dL
Hemoglobin	20000 mg/dL
Heparin	500 IU/dL
Ibuprofen	55 mg/dL
Icodextrin	2000 mg/dL
Isomalt	1000 mg/dL
Lactitol	1000 mg/dL
Maltitol	1000 mg/dL
Sorbitol	1000 mg/dL
L-Dopa	2.1 mg/dL
Maltose	5000 mg/dL
Methyl-L-dopa	1000 mg/dL
Salicylic acid	60 mg/dL
Sodium	460 mg/dL
Tolbutamide	100 mg/dL
Tolazamide	40 mg/dL
Triglycerides	3000 mg/dL
Uric acid	24 mg/dL
Xylose	300 mg/dL

Test Substance	Highest concentration tested with no significant interference
Xylitol	1000 mg/dL
Mannitol	5000 mg/dL
Mannose	200 mg/dL
Fenofibric acid	1.8 mg/dL
Canagliflozin	1.5×10^{-3} mg/dL
Amlodipine Besylate	1.8×10^{-3} mg/dL
Atorvastatin Calcium	8.4×10^{-3} mg/dL
Cilostazol	0.21 mg/dL
Prasugrel	0.105 mg/dL
Nortriptyline HCl	4.5×10^{-5} mg/dL
Budesonide	3.6×10^{-4} mg/dL
Dextromethorphan	9×10^{-4} mg/dL
Oxcarbazepine	2.58 mg/dL
Trihexyphenidyl HCL	0.015 mg/dL
Fluphenazine Decanoate	8.1×10^{-4} mg/dL
Levofloxacin	1.83×10^{-3} mg/dL
Glimiperide	0.0576 mg/dL
Benazeprilat	297 nmol/dL
Saxagliptin	0.72 mg/dL
Morphine	28.3 nmol/dL
Ursodiol	0.7836 mg/dL
Silodosin	0.01848 mg/dL
Letrozole	31.2 nmol/dL
Metformin	1.2 mg/dL
Sitagliptin	0.115 mg/dL
Glipizide	0.3 mg/dL
Humalog	100 U/L
Trulicity	450 mg/dL

The following limitations are included in the user manual and test strip package insert:

- *Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.*
- *Pralidoxime iodide level to > 5 mg/dL may affect the glucose results.*

4. Assay Reportable Range:

The reportable range is 10 to 800 mg/dL.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability:

The XPER Technology PREMIUM Pro Blood Glucose Monitoring System is traceable to the NIST (SRM) 917c glucose reference material. A method comparison was performed using the candidate device and YSI 2300 STAT Plus analyzer as the comparator method (see section VII.C.3 below).

Test Strip Stability:

Test strip stability was assessed through real-time open vial and closed vial studies. Protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims the closed vial and open vial stability of 12 months when stored at 34 to 86°F (1 to 30°C) and 10 to 90% relative humidity. The labeling instructs the user not to freeze the test strips.

6. Detection Limit:

Not applicable.

7. Assay Cut-Off:

Not applicable.

8. Accuracy (Instrument):

Not applicable.

9. Carry-Over:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Not applicable.

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Method Comparison/User Evaluation Study

The performance of the XPER Technology PREMIUM Pro Blood Glucose Monitoring System was established in the intended use environment using capillary fingerstick samples from 414 patients between the ages of 18 to 82 at 9 intended use settings that are representative of point-of-care settings with point-of-care operators.

The glucose levels tested ranged from 63 to 579 mg/L, with 24 results below 80 mg/dL and 24 results above 300 mg/dL. Testing was performed on 9 lots of XPER Technology PREMIUM Pro Blood Glucose Test Strips using 35 XPER Technology PREMIUM Pro Blood Glucose Meters. The clinical study included subjects that are representative of the intended patient population receiving a total of 69 unique medications representing 17 main drug classes.

The XPER Technology PREMIUM Pro Blood Glucose Monitoring results were compared to the YSI 2300 STAT Plus as the comparator method and the results from the clinical sites combined and presented below:

Results for Glucose Concentrations < 75 mg/dL:

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
8/13 (61.5%)	12/13 (92.3%)	13/13 (100%)	13/13 (100%)	0/13 (0%)

Results for Glucose Concentrations ≥ 75 mg/dL:

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
224/401 (55.9%)	356/401 (88.8%)	391/401 (97.5%)	399/401 (99.5%)	401/401 (100%)	0/401 (0%)

Accuracy at extreme glucose values:

An additional study was conducted to further assess the performance of the XPER Technology PREMIUM Pro Blood Glucose Monitoring System at the extreme upper and lower ends of the claimed measuring range. The sponsor altered 100 capillary whole blood samples from healthy donors, by spiking or allowing samples to glycolyze, to obtain 50 samples with glucose concentrations below 80 mg/dL (15.2 to 78.0 mg/dL) and 50 samples with glucose concentrations above 300 mg/dL (310 to 771 mg/dL) as measured by the comparator (YSI 2300). Samples were tested on the XPER Technology PREMIUM Pro Blood Glucose Monitoring System by intended use operators, using test strips from 3 lots and results compared to the results obtained on the comparator. The results are summarized below:

Results for Glucose Concentrations < 80 mg/dL:

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
45/50 (90.0%)	50/50 (100%)	50/50 (100%)	50/50 (100%)	0/50 (0%)

Results for Glucose Concentrations > 300 mg/dL:

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
38/50 (76.0%)	48/50 (96.0%)	50/50 (100%)	50/50 (100%)	50/50 (100%)	0/50 (0%)

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The sponsor includes the following in the labeling for the expected blood glucose values for people without diabetes:

Time of day	Normal plasma glucose range for people without diabetes (mg/dL or mmol/L)
Fasting* and before meal	Less than 100 mg/dL (5.6 mmol/L)
2 hours after meal	Less than 140 mg/dL (7.8 mmol/L)

American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2022 Jan; 45(Supplement 1): S17-S38. <https://doi.org/10.2337/dc22-S002>

* Fasting is defined as no caloric intake for at least 8 hours.

F Other Supportive Instrument Performance Characteristics Data:

1. Hematocrit Study:

The effect of hematocrit on the performance of the XPER Technology PREMIUM Pro Blood Glucose Monitoring System was evaluated using venous whole blood samples with hematocrit levels of 20 to 70 % (10, 15, 20, 25, 30, 35, 40, 42, 45, 50, 55, 60, 65 and 70 %), and at 7 glucose concentrations (10 to 30, 31 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400, and 600 to 800 mg/dL). The results obtained with the candidate system were compared to those obtained with the laboratory comparator method. The results of the study demonstrated adequate performance to support the claimed hematocrit range of 10 to 70%.

2. Altitude Study:

A simulated high-altitude study was conducted in a pressure chamber to simulate the effects of 4 altitudes from sea level (0 ft) and high-altitude (15,000 ft) on the XPER Technology PREMIUM Pro Blood Glucose Monitoring System. Venous whole blood samples adjusted to 7 glucose concentrations ranging from 62 to 581 mg/dL. The results of obtained with the candidate system were compared to those obtained with the laboratory comparator method.

The results support the claims that the XPER Technology PREMIUM Pro Blood Glucose Monitoring System blood glucose monitoring system functions as intended at altitudes up to the claimed altitude of 15,000 ft.

3. System Operating Conditions:

To evaluate device performance over varying operating temperature and humidity conditions, venous whole blood samples were adjusted to 3 glucose levels (65, 125, and 320 mg/dL). Testing was conducted under 4 combinations of temperature and relative humidity (RH) including 117°F (47°C) and 43°F (6°C) and 8% and 92% RH, and under the nominal condition of 77°F (25°C) at 60% RH. The results obtained with the candidate system were compared to those obtained with the comparator method. The results support the claims in the labeling that the XPER Technology PREMIUM Pro Blood Glucose Monitoring System blood glucose monitoring system can be used in conditions of 46 to 113°F (8 to 45°C) with relative humidity of 10% to 90%.

4. Sample Volume Study:

The sponsor performed a study to support the claimed minimum sample volume of 0.5 µL for the XPER Technology PREMIUM Pro Blood Glucose Monitoring System. Venous whole blood samples with 3 glucose concentration ranges (50 to 65, 100 to 120 and 200 to 250 mg/dL) were tested at six sample volumes (0.3, 0.4, 0.5, 0.6, 0.7 and 0.8 µL) using three lots of test strips. Values obtained were compared to the comparator method. The sponsor provided validation studies demonstrating that with blood volumes below 0.5 µL, the insufficient sample volume error message functioned as intended. Results support the claimed minimum sample volume of 0.5 µL for the system.

5. Flex Studies:

The following additional flex studies were performed with the candidate system: drop/shock, early test strip removal, intermittent sampling, sample outside measuring range, sample perturbation, shipping, used test strips, incorrect test strips and vibration testing. The results demonstrated that the performance of the XPER Technology PREMIUM Pro Blood Glucose Monitoring System is robust under these expected use conditions.

6. Infection Control Testing:

The device is intended for multiple-patient use. Disinfection efficacy studies were performed on the exterior meter materials by an outside commercial testing laboratory, demonstrating complete inactivation of Hepatitis B Virus (HBV) with the chosen disinfectant Clorox Healthcare™ Bleach Germicidal Wipe (EPA No.: 67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 27,500 cycles of cleaning and disinfection using the chosen disinfectant. The robustness studies were designed to simulate cleaning and disinfection over the 5-year multi-patient use life of the meter. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. Electromagnetic Compatibility and Electrical Safety:

The sponsor provided documentation certifying that acceptable electrical safety and electromagnetic compatibility (EMC) testing had been performed and the system was found to be compliant.

8. Software and Cybersecurity:

The sponsor provided software and cybersecurity documentation that was reviewed and found to be acceptable.

9. Glucose Test Strip Lot Release Protocol:

The test strip lot release protocol and criteria for the lot release of the XPER Technology PREMIUM Pro Blood Glucose Test Strips with the XPER Technology PREMIUM Pro blood glucose meter was reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.