Food and Drug Administration
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Silver Spring, MD 20993-0002
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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

k190579

B Applicant

TaiDoc Technology Corporation

C Proprietary and Established Names

TD-4183 Blood Glucose Monitoring System

D Regulatory Information

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

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Glucose in capillary whole blood obtained from the fingertip

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 TD-4183 Blood Glucose Monitoring System consists of the TD-4183 Blood Glucose meter and the TD-4183 Blood Glucose Test Strips.

The TD-4183 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. This system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of the diabetes control program. It is intended to be used by single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on noenates.

C Special Conditions for Use Statement(s):

- Over the counter
- For in vitro diagnostic use
- For single-patient use only
- This system should not be used for the diagnosis of, or screening for diabetes.
- This system is not for use on patients with abnormally low blood pressure or those who are in shock
- Test results may be lower than the actual values or inacccurate if the individual is hypotensive, in a hyperglycemic-hyperosmolar state (with or without ketosis)
- This system is not for use with neonates
- This system should not be used on critically ill patients.
- This system should not be used on patients with impaired peripheral circulation or severe dehydration.
- Altitudes above 15,000 feet may cause inaccurate results.
- The device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficincey Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other blood borne pathogens.

D Special Instrument Requirements:

TD-4183 Blood Glucose Monitoring System

IV Device/System Characteristics:

A Device Description:

TD-4183 Blood Glucose Monitoring System consists of the TD-4183 Blood Glucose meter, TD-4183 Blood Glucose test strips, Owners' manual, Protective Wallet, Warranty card, Daily Log Book, One 1.5V AAA alkaline battery, a Quick Start Guide, TD-4183 Blood glucose Control Solutions, sterile lancets and lancing device.

B Principle of Operation:

TD-4183 Blood Glucose Monitoring System measures the amount of glucose in whole blood quantitative using fresh capillary whole blood from the fingertip. Amperometric technology is used for the detection of glucose from testing the strip (with whole blood sample) on the meter. Reagent consisting of GDH-FAD and mediator is deposited onto the reaction cell section of the test strip with printed electrodes. When a drop of whole blood is applied to the reaction cell on the test strip, glucose in the blood sample reacts in the presence of GDH-FAD and mediator, and the reaction yields electrons. Thus, a current signal is produced from the reaction and detected by the meter. The detected current signal is then calculated by the meter and the resulting glucose concentration is then displayed on the meter display.

C Instrument Description Information:

Modes of Operation	**Yes**	**No**
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☐	☒
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☐	☒
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   TD-4183 Blood Glucose Monitoring System

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 system is intended to be used with capillary whole blood from the fingertip. The whole

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 meter is automatically coded.

5. Quality Control:

   TD-4183 Blood Glucose Monitoring System Control Solutions are aqueous solutions that can be purchased separately. Recommendations on when to perform a control solution test are provided in the labeling. Acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges. The control solution readings are not included in the average of the patient results when the measurements are performed in the "QC" measurement mode.

V Substantial Equivalence Information:

A Predicate Device Name(s):

TD-4277 Blood Glucose Monitoring System, Model 4277

B Predicate 510(k) Number(s):

k100322

C Comparison with Predicate(s):

Device & Predicate Device(s):	K190579	K100322
Device Trade Name	TD-4183 Blood Glucose Monitoring System (candidate)	TD-4277 Blood Glucose Monitoring System (predicate)
General Device Characteristic Similarities		
Indications for use	Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip as an aid in monitoring the effectiveness of the diabetes control program.	Same
Detection method	Amperometry	Same

Strip Enzyme	Glucose Dehydrogenase -FAD	Same
Sample Volume	0.5 µL	Same
Measurement units	mg/dL	Same
User interface	LCD and buttons	Same
General Device Characteristic Differences		
Measuring range	20-650 mg/dL	20-600 mg/dL
Hematocrit range	20-65%	20-60%
Strip storage	35.6°F to 86°F, 10% to 85% Relative Humidity (RH)	35.6°F to 89.6°F, <85% RH

VI Standards/Guidance Documents Referenced:

- Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use, Guidance for Industry and Food and Drug Administration Staff. October 11, 2016.
- Clinical and Laboratory Standards Institute (CLSI) EP5-A2, 2004. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition, Vol. 24, No. 25.
- IEC 61010-1, Edition 3.0: 2010, International Standard. Medical electrical equipment Part 1-11: General requirement for basic safety and essential performance
- IEC 61010-2, Edition 3.0: 2007, International Standard. Medical electrical equipment Part 1-11: General requirement for basic safety and essential performance
- IEC 62366 Medical devices – Application of usability engineering to medical devices.
- ISO – 14971: Medical Devices -Application Of Risk Management To Medical Devices.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability (within-run precision):
The sponsor performed a repeatability study (within day) precision study using venous whole blood adjusted to 5 different glucose concentration levels (approximately 44.58, 86.67, 138.58,234.36, and 345.35 mg/dL). Each glucose concentration level was analyzed in replicates of 10 with 3 test strips lots, and 10 meters, for a total of 300 tests per glucose level. Results are summarized in the table below:

Glucose	Average	SD	CV
Level 1	44.58	1.952	4.38
Level 2	86.67	3.509	4.05
Level 3	138.58	4.894	3.53
Level 4	234.36	8.037	3.43
Level 5	345.35	11.817	3.42

Intermediate Precision:

Intermediate (day to day) precision was performed using 5 levels of glucose control solutions with mean glucose concentrations of (46.05, 66.86, 126.32, 197.57, and 317.36 mg/dL). Testing was performed for 10 days with 3 test strip lots. For each level, on each day, 10 meters were used for testing, with 1 replicate collected per meter for a total of 10 replicates per day for each glucose level, for a total of 300 tests per glucose level. Results are summarized below:

Glucose	Mean	SD	CV
Level 1	46.05	2.014	4.37
Level 2	66.86	2.908	4.35
Level 3	126.32	4.470	3.54
Level 4	197.57	6.954	3.52
Levels 5	317.36	10.767	3.39

2. Linearity:

Linearity testing was evaluated with test strips from 3 lots and 11 mixed pools of venous whole blood samples with glucose concentrations of 18, 40, 63, 95, 129, 169, 231, 316, 408, 559 and 679 mg/dL as measured by the comparator method, YSI 2300. Each level was measured in replicate of 15 and the values obtained on TD-4183 Blood Glucose Monitoring System compared with those obtained from YSI 2300. Linear regresion analysis of the results yielded the following:

Lot	Slope	y-intercept	R^2
1	1.0013	0.6521	0.9973
2	1.0077	0.2259	0.9978
3	1.005	1.5608	0.9976

The results of the study support the sponsor's claimed glucose measuring range of 20-650 mg/dL. If a sample is less than 20 mg/dL, the result is flagged by the meter as LO. If the result is greater than 650 mg/dL, the result is flagged by the meter as HI. This low and high functions were validated and demonstrated to function as intended.

3. Analytical Specificity/Interference:

Interference studies were performed by spiking venous whole blood to achieve 3 glucose levels (60-80 mg/dL, 120-140 mg/dL, and 240-300 mg/dL). Each of these samples were divided into a test pool with the potential interferent added and a control sample with no added interferent. Each sample was measured using 10 meters with 3 lots of the test strips, for a total of 30 replicates per sample. Results on the candidate meter from the test samples were compared to results obtained on the candidate meter from the control sample. The highest tested concentrations at which no significant interference was observed (defined by the sponsor as ≤ 10% bias) are presented in the following table:

Substances	Highest concentration tested with no significant interference
Acetaminophen	6.25 mg/dL
Ascorbic Acid	5 mg/dL
Bilirubin	20 mg/dL
Cholesterol	500 mg/dL
Creatinine	30 mg/L
Dopamine	1.25 mg/dL
Galactose	250 mg/dL
Genetisic acid	5 mg/dL
Glutathione	30mg/dL
Ibuprofen	55 mg/dL
Icodextrin	2000 mg/dL
Isomalt	1000 mg/dL
L-Dopa	0.7 mg/dL
Lactitol	1000 mg/dL
Maltitol	1000 mg/dL
Mannitol	5000 mg/dL
Maltose	1000 mg/dL
Mannose	125 mg/dL
Methyldopa	1.875 mg/dL
Pralidoxime Iodide	5 mg/dL
Salicyclic Acid	60 mg/dL
Sodium	460 mmol/L
Sorbitol	1000 mg/dL
Tolbutamide	12.5mg/dL
Uric Acid	10 mg/dL
Xylose	3.125 mg/dL
Xylitol	1000 mg/dL

Statements from labeling –

- Acetaminophen in your blood (> 6.25 mg/dL) might affect the reliability of your blood glucose results. If you are taking Tylenol, or other acetaminophen containing drugs, your glucose results may not be reliable. If you are unsure, then ask your healthcare professional.
- If you have a disease or condition that elevates your blood uric acid level (>10 mg/dL), such as gout, your blood glucose results may not be reliable. If you are unsure, then ask your healthcare professional.
- If you are taking high doses of Tolazamide (> 12.5 mg/dL in your blood), then you should know that this drug might affect the reliability of your blood glucose results. If you are unsure, then ask your healthcare professional.
- 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. If you are unsure, then ask your healthcare professional.

4. Assay Reportable Range:

   Assay reportable range is 20-650 mg/dL supported by the Linearity assay above (Section A.2).

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

   The system is traceable to NIST SRM #917c glucose reference material. A method comparison was performed using the candidate device and YSI 2300 as the comparator method.

   Test Strip Stability:

   TD-4183 Blood Glucose test strip stability was assessed using accelerated and real time stability studies. Protocols and acceptance criteria were reviewed and found acceptable. The labeling includes claims that the test strips are stable for 6 months after opening and 24 months unopened when stored between of 35.6ºF to 86ºF (2ºC-30ºC) and 10-85% relative humidity.

6. Detection Limit:

   The reportable range for the TD-4183 Blood Glucose Monitoring System is 20 to 650 mg/dL supported by the linearity assay study above (Section A.2)

7. Assay Cut-Off:

   Not Applicable.

8. Accuracy (Instrument):

   Not Applicable.

9. Carry-Over:

   Not Applicable.

B Comparison Studies:

Method Comparison with Predicate Device:

Lay user Performance study:

To assess the performance of the TD-4183 Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed studies in multiple sites with 350 English speaking participants. The users were responsible for obtaining their own fingertip capillary sample and performing a blood glucose test using only the instructions from the product labeling. A total of 24 meters and 3 lots of test strips were used. Results were analyzed by comparing the blood glucose results obtained by the lay users with the TD-4183 Blood Glucose Monitoring Systems

against results obtained with a laboratory-based comparator method (YSI 2300 analyzer). The glucose concentrations in the samples ranged from 45-390 mg/dL, as measured by the YSI 2300 Results are summarized in the tables below:

For glucose concentrations < 75 mg/dL:			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
11/15 (73.3%)	15/15 (100%)	15/15 (100%)	15/15 (100%)

For glucose concentrations > 75 mg/dL:			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
149/335 (44.5%)	275/335 (82.1%)	327/335 (97.6%)	335/335 (100%)

Combined glucose concentrations across the measuring range:			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
156/350 (44.6%)	287/350 (82.0%)	341/350 (97.4%)	350/350 (100%)

Accuracy at Extreme Glucose Study:

A study to evaluate the performance of TD-4183 Blood Glucose Monitoring Systems in the extreme lower and upper ends of the claimed range was performed using 50 altered samples with glucose concentrations below 80 mg/dL, and 50 samples greater than 250 mg/dL. Samples were altered by spiking or glycolysis in order to obtain the appropriate glucose concentrations. Samples were tested on TD-4183 Blood Glucose with test strips from 3 lots and compared to the results obtained on YSI 2300 analyzer. The glucose concentrations in the samples ranged from 23-76 mg/dL on the lower end and 276 -641 mg/dL on the higher end, as measured by the YSI 2300. Results are summarized below:

For glucose concentrations < 80 mg/dL:			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
46/50 (92.0%)	50/50 (100%)	50/50 (100%)	50/50 (100%)

For glucose concentrations >250mg/dL:			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
14/50 (24.0%)	31/50 (62.0%)	49/50 (98.0%)	50/50 (100%)

The accuracy performance demonstrated in the lay-user and extreme glucose studies was determined to be adequate and to not have a significant clinical risk to the users due to the direction of the bias observed with samples containing high glucose concentrations.
The labeling instructs users to contact their health professional immediately if they obtain lower than expected glucose results.

Readability:

Flesch-Kincaid readability assessment was conducted, and the results demonstrated that the User Manual and the test strip package insert were written at an 8th grade level or less.

1. 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):

   Not Applicable.

D Clinical Cut-Off:

Not Applicable.

E Expected Values/Reference Range:

The sponsor includes the following expected glucose values in their labeling:

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

Source: American Diabetes Association. Standards of Medical Care in Diabetes-2018 Jan;41(Supplement 1): S1-S2.

F Other Supportive Instrument Performance Characteristics Data:

1. Hematocrit Study:
   To evaluate the effect of hematocrit on the TD-4183 Blood Glucose Monitoring System, venous blood samples were adjusted to hematocrit levels of 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, and 65%. Each hematocrit level was adjusted to achieve five concentrations of, (42.0, 79.5, 129.5,224.0, and 384 mg/dL. Each sample was tested using TD4183 Blood Glucose Monitoring System 10 meters with test strips from 3 lots: The values were compared with the average of 4 glucose measurement obtained from YSI 2300 analyzer. The percent biases relative to the comparator method demonstrated were acceptable within the claimed hematocrit range of 20 to 65%.

2. Altitude Study:
   To evaluate the effect of altitude on the TD4183 Blood Glucose Monitoring System, a study was conducted using venous whole blood samples adjusted with 7 concentration

levels of glucose ranging from 51-650 mg/dL. Samples were placed under conditions to simulate 4 different altitude condition from sea level to 4,400 meters (15, 000feet). Each blood sample was tested using 4 TD4183 Blood Glucose Monitoring System with test strips from 1 lot. The values obtained were compared with the values obtained with the YSI 2300 analyzer outside of the pressurized chamber. The results demonstrated acceptable bias to YSI 2300 to support the claim in the labeling that glucose measurement performance of the TD4183 Blood Glucose Monitoring System is maintained at altitudes ranging sea level up to 4,500 meters (15, 000 feet).

3. Operating Conditions Study:
   The effect of temperature and relative humidity on the TD4183 Blood Glucose Monitoring System was evaluated using venous whole blood samples adjusted to approximately 65, 125, and 320 mg/dL. Testing was conducted under the following temperature and relative humidity (RH) combinations: 45^0C(113°F) and 50C(41°F), at 5% to 90% RH each and at 25^0C(77^0F) at 60% RH. Four TD4183 Blood Glucose Monitoring System and 3 lots of test strips were used. Values measured on TD4183 Blood Glucose Monitoring System were compared to results from the comparator YSI 2300. The study results support the operating conditions claim of 46.4°F - 113°F (8-45°C) with relative humidity of 10% to 90%.

4. Volume Study:
   The sponsor performed a study to support the claimed minimum sample volume of 0.5 µL for the TD-4183 Blood Glucose Monitoring System. Venous whole blood samples with three levels of glucose concentrations (61.9, 114.0, 243 mg/dL) were tested at six sample volumes (0.3,0.4, 0.5, 0.6, 0.7, and 0.8 µL) using 3 lots of the test strips and 5 meters. Values obtained were compared to YSI 2300 values. The meter has an error message displayed if enough blood is not added to the test strip. This feature was validated and was shown to function as intended. Results support the claimed minimum sample volume of 0.5 µL

5. Flex Studies:
   Intermittent sampling, sample perturbation, testing with used test strips, drop, vibration and shipping testing was completed. The testing performed demonstrated that the device is robust to intermittent sampling, sample perturbation, drop/shock, and vibration, and that an error message is returned to the user if a used test strip is inserted into the meter.

6. Infection Control Studies:
   The TD-4183 Blood Glucose Monitoring System in this submission is intended for single-patient use only. Disinfection efficacy studies were performed on the meter materials by an outside commercial laboratory, demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant Micro-Kill+™ Disinfecting Wipes (EPA Registration Number 59894-10-37549). Robustness studies were also performed by the sponsor using the TD-4183 Blood Glucose Monitoring System demonstrating that there was no change in the performance of the system or in the external materials of the meter after 260 cycles of cleaning and disinfection using the chosen disinfectant. The robustness studies were designed to simulate cleaning and disinfecting over the 5-year single-patient use life of the meter. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. Electrical Safety and EMC testing:
   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. Test Strip Lot Release Protocol:
   The test strip lot release protocol and acceptance criteria were 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.