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

I Background Information:

A 510(k) Number

K223722

B Applicant

Mio Labs Inc.

C Proprietary and Established Names

MIO 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 drawn from the fingertip

C Type of Test:

Quantitative amperometric assay (glucose oxidase)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

MIO Blood Glucose Monitoring System is comprised of the MIO Blood Glucose Meter and the MIO Blood Glucose Test Strips. MIO Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-testing outside the body (in vitro diagnostic use), and should only be used by a single person and should not be shared.

C Special Conditions for Use Statement(s):

- OTC - Over The Counter
- For single-patient use only.
- Not for use on critically ill patients, severely hypotensive individuals, patients in shock, dehydrated patients, or in a hyperglycemic-hyperosmolar state with or without ketosis.
- Not for neonatal use.
- Not for screening for or diagnosis of diabetes mellitus.
- Do not use at altitudes above 10,413 ft (3,174 meters) above sea level.
- This meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

D Special Instrument Requirements:

MIO Blood Glucose Meter

IV Device/System Characteristics:

A Device Description:

The MIO Blood Glucose Monitoring System is designed to quantitatively measure the glucose concentration in fresh capillary whole blood obtained from the fingertip. The MIO Blood Glucose Monitoring System consists of the MIO Blood Glucose Meter, the MIO Blood Glucose Test Strips, three levels of MIO Control Solutions (Levels 1, 2 and 3) and the MIO Lancing Device with MIO Lancets. The MIO test strips, control solutions and lancing device with lancets are sold separately. MIO Blood Glucose Monitoring System reports glucose results as plasma glucose.

B Principle of Operation:

The glucose measurement is achieved by using an amperometric detection method. The test is based on the measurement of an electrical current caused by the reaction of glucose with the reagents on the electrode of the test strip. When a drop of blood is applied to the test strip it is pulled into the test strip through capillary action. Glucose in the sample reacts with glucose oxidase and the mediator in the test strip generating electrons and producing a current that is proportional to the glucose concentration in the sample. After the reaction time, the detected current is calculated by the meter and the resulting glucose concentration is displayed by the meter.

C Instrument Description Information:

1. Instrument Name:

   MIO 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 system is intended to be used with capillary whole blood from the finger only. 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:

   Three levels of glucose control solutions are available for use with this system and can be purchased separately. Recommendations on when to test with control solutions are provided in the labeling. Acceptable ranges for each level of control solution are 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 automatically marked by the meter as control results and are not included in the patient result averages.

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 premarket 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):
VivaChek Ino Smart Blood Glucose Monitoring System

B Predicate 510(k) Number(s):
K173140

C Comparison with Predicate(s):

Device & Predicate Device(s):	K223722	K173140
Device Trade Name	MIO Blood Glucose Monitoring System	VivaChek Ino Smart Blood Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	It is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control.	Same
Strip Chemical Composition	Glucose oxidase	Same
Sample Type	Fresh capillary whole blood	Same
Measurement Range	20-600 mg/dL	Same
Sample Volume	0.8 µL	Same
Test Time	5 seconds	Same
General Device Characteristic Differences		
Data Transmission	4G	Bluetooth

VI Standards/Guidance Documents Referenced:

FDA Guidance Document: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter 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 Precision (Repeatability)

Within-run precision studies were performed using venous whole blood samples adjusted to 5 glucose concentration levels (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL). Each sample was tested in replicates of 10 with 3 lots of test strips and 10 meters for a total of 300 tests per glucose level. Results are summarized below:

Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	Lot 1	100	40.0	1.8	4.4%
	Lot 2	100	39.9	1.8	4.5%
	Lot 3	100	39.6	1.8	4.7%
	Combined	300	39.8	1.8	4.5%
51-110	Lot 1	100	70.8	2.1	3.0%
	Lot 2	100	71.1	2.1	3.0%
	Lot 3	100	69.7	2.4	3.4%
	Combined	300	70.5	2.3	3.2%
111-150	Lot 1	100	128.7	3.8	2.9%
	Lot 2	100	128.1	3.2	2.5%
	Lot 3	100	127.0	3.7	2.9%
	Combined	300	127.9	3.6	2.8%
151-250	Lot 1	100	196.6	5.2	2.6%
	Lot 2	100	202.4	5.7	2.8%
	Lot 3	100	198.0	5.3	2.7%
	Combined	300	199.0	5.9	3.0%
251-400	Lot 1	100	350.4	9.5	2.7%
	Lot 2	100	353.4	10.3	2.9%
	Lot 3	100	345.0	9.0	2.6%
	Combined	300	349.6	10.2	2.9%

Intermediate Precision (Between Run)

Intermediate (between run) precision was evaluated using five levels of glucose control solutions (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL), 3 test strip lots, and 10 meters. Each control solution level was measured once a day for 10 days with each meter and test strip lot, for a total of 100 replicates per control solution level per test strip lot for a total of 300 replicates for each glucose control solution level. Results are summarized below:

Control Levels (mg/dL)	Strip lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	Lot 1	100	40.1	1.9	4.80%
	Lot 2	100	40.1	1.7	4.20%
	Lot 3	100	39.7	1.8	4.60%
	Combined	300	40.0	1.8	4.60%
51-110	Lot 1	100	70.1	2.1	3.10%
	Lot 2	100	70.2	2.0	2.80%
	Lot 3	100	70.1	2.0	2.80%
	Combined	300	70.1	2.0	2.90%
111-150	Lot 1	100	130.0	3.1	2.40%
	Lot 2	100	129.5	3.1	2.40%
	Lot 3	100	130.2	3.1	2.30%
	Combined	300	129.8	3.1	2.40%
151-250	Lot 1	100	199.4	4.7	2.40%
	Lot 2	100	198.9	4.4	2.20%
	Lot 3	100	200.1	4.7	2.30%
	Combined	300	199.5	4.6	2.30%
251-400	Lot 1	100	349.3	7.9	2.30%
	Lot 2	100	350.8	8.4	2.40%
	Lot 3	100	350.4	7.5	2.10%
	Combined	300	349.9	7.9	2.30%

2. Linearity:

The linearity of the glucose measurement was evaluated using venous whole blood either glycolyzed or spiked with glucose. Eleven whole blood samples were adjusted to the following glucose concentration ranges (as measured by the YSI 2300 comparator method): 20, 78, 136, 194, 252, 310, 368, 426, 484, 542, and 600 mg/dL. The summary of the linear regression analysis for each lot was as follows:

Test Strip Lot #	**Slope**	**y-intercept**	**R^2 value**
Lot 1	0.9982	-1.276	0.9975
Lot 2	0.9945	-1.1411	0.9982
Lot 3	0.9949	0.1534	0.9973
Combined	0.9959	-0.7546	0.9976

The results of the study support the linearity of the system across the sponsor's claimed glucose measuring range of 20-600 mg/dL. If a sample result is less than 20 mg/dL glucose,

the result is flagged by the meter as “Lo”. If a sample result exceeds 600 mg/dL glucose, the result is flagged by the meter as “Hi”. The “Lo” and “Hi” functions were validated by the sponsor and were demonstrated to function as intended.

3. Analytical Specificity/Interference:

To assess potential interferences, the sponsor used venous whole blood samples adjusted to achieve 3 glucose concentration ranges: 50-70, 110-130, and 225-270 mg/dL. Each of these samples was divided into a test pool and a control pool, with each of the potential endogenous and exogenous interfering substances added to the test pool. The % difference between the test sample and the control sample was calculated using the mean of 10 replicates for each of the 3 strip lots tested. The highest tested concentrations at which no significant interference was observed (defined by the sponsor as less than ±10% bias between the test and control samples) are presented in the following table:

Potential Interfering Substance	**Highest Concentration with no Significant Interference**
Acetaminophen	20 mg/dL
Ascorbic acid	6 mg/dL
Conjugated Bilirubin	50 mg/dL
Unconjugated Bilirubin	40 mg/dL
Cholesterol	500 mg/dL
Creatinine	15 mg/dL
Dopamine	20 mg/dL
EDTA	200 mg/dL
Galactose	60 mg/dL
Gentisic acid	27.8 mg/dL
Reduced Glutathione	92.9 mg/dL
Hemoglobin	20000 mg/dL
Heparin	800 IU/dL
Ibuprofen	50 mg/dL
L-Dopa	3 mg/dL
Maltose	480 mg/dL
Mannitol	1800 mg/dL
Methyldopa	10.5 mg/dL
Salicylic acid	60 mg/dL
Sodium	180 mmol/L
Tolbutamide	100 mg/dL
Tolazamide	40 mg/dL
Triglycerides	3000 mg/dL
Uric acid	24 mg/dL
Xylose	200 mg/dL
Sorbitol	0.09 mg/dL
Lactose	25 mg/dL
Tetracycline	1.5 mg/dL

Potential Interfering Substance	Highest Concentration with no Significant Interference
Xylitol	0.09 mg/dL
Lactitol	0.09 mg/dL
Isomalt	0.09 mg/dL
Maltitol	0.09 mg/dL

The sponsor has included the following information in the labeling:

- Do not test your blood glucose during or soon after a xylose absorption test. Xylose in the blood can give inaccurate results with this meter.

4. Assay Reportable Range:

   20 – 600 mg/dL glucose

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

   The glucose measurement functionality of the MIO Blood Glucose Monitoring System is traceable to the NIST SRM 917c glucose reference material. The method comparison/lay-user study was performed using the YSI 2300 STAT Plus Glucose Analyzer as the comparator method (see section VII.C.3).

   Open and Closed Vial Stability
   Test strip stability was assessed using accelerated and real time stability studies. Testing protocols and acceptance criteria were reviewed and found to be acceptable. The labeling includes claims that the MIO Blood Glucose Test Strips are stable for 6 months after opening and 24 months unopened when stored between 36-86ºF and 10-90% relative humidity.

6. Detection Limit:

   Please see the linearity section above, VII.A.2

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:

   Please refer to lay user study below in section VII.C3.

2. Matrix Comparison:

   Not applicable. The device is only intended for use with fresh capillary whole blood drawn from the fingertip.

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/Lay User Performance Study:
   To assess the performance of the MIO Blood Glucose Monitoring System in the hands of lay users, the sponsor performed a study with 353 lay user participants who collected and tested their own fingertip capillary blood samples using only the instructions from the product labeling in English. The glucose concentrations in the samples ranged from 48-448 mg/dL, including 56 native samples with glucose levels <80 mg/dL and 68 samples with glucose level >250 mg/dL, as measured by the comparator method (YSI 2300 analyzer). Results were analyzed by comparing blood glucose results obtained from the MIO Blood meter by the lay user against the laboratory comparator value obtained by healthcare professionals. Results are summarized in the tables below:

	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Fingertip	241/352 (68.5%)	338/352 (96.0%)	352/352 (100%)	352/352 (100%)

   Regression analysis results:
   $y = 0.9933x + 0.3766$; $R^2 = 0.9883$

   Usability:
   At the end of the lay-user study, each participant was asked to complete a usability questionnaire regarding ease of understanding of information in the user manual and the ease of use when performing a blood glucose test. The sponsor's analysis of the questionnaire responses demonstrated that the participants were satisfied with the ease of operation by

following the instructions for use in the User's Manual and with the overall performance of the MIO Blood Glucose Monitoring System.

Labeling Readability:
The readability of the user manual, test strip package insert, and quick reference guide were evaluated using a Flesch-Kincaid analysis and demonstrated that the readability was less than an 8th grade level.

Extreme Glucose Study:
An accuracy study was performed to evaluate the performance of the MIO Blood Glucose Monitoring System with 105 capillary samples containing extreme glucose concentrations at the extreme lower and upper ends of the claimed glucose measuring range. Fifty three (53) samples were altered by glycolysis to achieve glucose concentrations below 80 mg/dL and 52 samples were spiked to achieve glucose concentrations greater than 250 mg/dL. Results on the candidate device using 3 test strip lots were compared to the results obtained using the comparator method (YSI 2300) and are summarized below:

System accuracy results for extreme low (<80mg/dL) glucose readings			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
35/53 (73.6%)	52/53 (98.1%)	53/53 (100%)	53/53 (100%)
System Accuracy results for extreme high (>250mg/dL) glucose readings			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
34/52 (65.4%)	50/52 (96.2%)	52/52 (100%)	52/52 (100%)

D Clinical Cut-Off:

Not Applicable.

E Expected Values/Reference Range:

The expected blood glucose values for people without diabetes:
< 100 mg/dL fasting
<140 mg/dL 2 hours after a meal

Reference: American Diabetes Association; Standards of Care in Diabetes—2023 Abridged for Primary Care Providers. Clin Diabetes 2 January 2023; 41 (1): 4–31.

F Other Supportive Instrument Performance Characteristics Data:

1. Hematocrit study
   The effect of different hematocrit levels was evaluated using venous whole blood samples with hematocrit levels of 20-70% (20, 25, 30, 35, 42, 50, 55, 60, 65, and 70%) at five levels of glucose (40, 70, 130, 200, and 325 md/dL). Each sample was tested in replicates of 10 using 10 meters and three test strip lots. Results from the meter were compared to results obtained using a laboratory-based comparator measurement. The evaluation of bias and percent bias relative to values obtained on the YSI 2300 analyzer demonstrated acceptable performance across the claimed hematocrit range of 20-70%.

2. System Operating Conditions Testing

   The sponsor performed an operating condition study using venous whole blood samples adjusted to 3 glucose levels (65.2, 112.5, and 351.0 mg/dL). Testing was conducted under the following five temperature and relative humidity (RH) combinations: 113°F (45°C) and 41°F (5°C), at 10% and 90% RH each and at 73°F (23°C) at 40% RH. The candidate system results were compared to results from the YSI 2300 comparator method. The results support the claims in the labeling that the system can be used in conditions of 41–113°F (5-45°C) with relative humidity of 10 to 90%.

   Altitude Effects

   To evaluate the effects of altitude on the MIO Blood Glucose Monitoring System a study was conducted using fingerstick whole blood samples altered to achieve 15 glucose concentrations ranging from 45.0 to 486 mg/dL. Each sample was tested using 3 test strip lots and 6 glucose meters at 10,413 feet. The candidate system results were compared to those obtained with the comparator method (YSI 2300 analyzer). The results support the claims that the system functions as intended at altitudes up to the claimed altitude of 10,413 feet.

3. Sample Volume

   Three venous blood samples were prepared at three glucose range intervals (59.1, 110.5, and 223.0 mg/dL) and were tested at different sample volumes (0.6, 0.7, and 0.8 µL). Meter results were compared against the YSI 2300 comparator method measurements. Results support the claimed minimum sample volume of 0.8 µL. The sponsor provided validation studies demonstrating that with blood volumes below 0.8 µL, the insufficient sample volume error message functioned as intended.

4. Flex Studies

   The following additional flex studies were performed with the MIO Blood Glucose Monitoring System: sample perturbation, intermittent sampling, sample outside measuring range, used test strips, drop, and shipping testing. The testing demonstrated that the device is robust under these conditions.

5. 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.

6. Infection Control Testing

   The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the external meter materials by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Healthcare Bleach Germicidal Wipes (EPA Registration #67619-12). A robustness study was also conducted by the sponsor demonstrating that there was no change in performance or in the external materials of the meter after 608 cleaning and disinfection cycles using the Clorox Healthcare Bleach Germicidal Wipes. The robustness studies were designed to simulate 5 years of single-patient device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. Glucose Test Strip Lot Release Protocol
   The glucose test strip lot release protocols and 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.