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

I Background Information:

A 510(k) Number

K262873

B Applicant

Trividia Health, Inc.

C Proprietary and Established Names

TRUE METRIX GO Self Monitoring Blood Glucose System
TRUE METRIX Self Monitoring Blood Glucose 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:

Modifications to reassign test strip error conditions caused by very high glucose levels (>900 mg/dL) from the "E-5" error code to a new "EHi" error code for the TRUE METRIX GO Self Monitoring Blood Glucose System, and the activation of the data transfer function via a USB connection to a personal computer for the TRUE METRIX GO Self Monitoring Blood Glucose System and TRUE METRIX Self Monitoring Blood Glucose System.

B Measurand:

Glucose in fresh capillary whole blood

C Type of Test:

Quantitative amperometric assay (FAD-Glucose Dehydrogenase)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

TRUE METRIX GO Self Monitoring Blood Glucose System
The TRUE METRIX GO Self Monitoring Blood Glucose System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The TRUE METRIX GO Self Monitoring Blood Glucose System is intended to be used by a single person and not shared.

The TRUE METRIX GO Self Monitoring Blood Glucose System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The TRUE METRIX GO Self Monitoring Blood Glucose System should not be used for the diagnosis or screening of diabetes, for neonatal use or for alternative site testing.

The TRUE METRIX Self Monitoring Blood Glucose Test Strips are for use with the TRUE METRIX GO Self Monitoring Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip.

TRUE METRIX Self Monitoring Blood Glucose System
The TRUE METRIX Self Monitoring Blood Glucose System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm. The TRUE METRIX Self Monitoring Blood Glucose System is intended to be used by a single person and not shared.

The TRUE METRIX Self Monitoring Blood Glucose System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The TRUE METRIX Self Monitoring Blood Glucose System should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The TRUE METRIX Self Monitoring Blood Glucose Test Strips are for use with the TRUE METRIX Self Monitoring Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm.

C Special Conditions for Use Statement(s):

The following Special Conditions for Use Statements apply to the TRUE METRIX GO and TRUE METRIX Self Monitoring Blood Glucose Systems:

- For over-the-counter use.
- For *in vitro* diagnostic use only.
- Not for neonatal use.

- For single patient use only.
- Do not use for diagnosis of or screening of diabetes.
- Critically ill patients should not be tested with this device.
- Inaccurate results may occur in severely hypotensive individuals or in dehydrated patients or patients in shock. Inaccurate results may occur for individuals experiencing a hyperglycemichyperosmolar state, with or without ketosis.
- Testing at altitudes greater than 10,200 ft may cause inaccurate results.

The following Special Conditions for Use Statements apply to the TRUE METRIX GO Self Monitoring Blood Glucose System:

- Not for alternative site testing.

The following Special Conditions for Use Statements apply to the TRUE METRIX Self Monitoring Blood Glucose System:

- Alternative site sample results may be different from fingertip sample results when glucose levels are changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise).
- Alternative site (forearm) testing should not be used to calibrate continuous glucose monitoring systems (CGMS) or for insulin dose calculations.
- Do not rely on test results at an alternative sampling site, but use samples taken from the fingertip, if any of the following applies:
  - you think your blood sugar is low.
  - you are not aware of symptoms when you become hypoglycemic.
  - the results do not agree with the way you feel.
  - after a meal.
  - after exercise.
  - during illness.
  - during times of stress.

D Special Instrument Requirements:

TRUE METRIX GO Self Monitoring Blood Glucose Meter
TRUE METRIX Self Monitoring Blood Glucose Meter

IV Device/System Characteristics:

A Device Description:

The TRUE METRIX GO and the TRUE METRIX Self Monitoring Blood Glucose Systems are comprised of the TRUE METRIX GO or TRUE METRIX Self Monitoring Blood Glucose Meter, the TRUE METRIX Self Monitoring Blood Glucose Test Strips, TRUE METRIX control solutions (Level 1, 2, and 3), the TRUEdraw Mini Lancing Device or TRUEdraw lancing device, and the TRUEplus Sterile or TRUEplus Safety lancets.

The meters, test strips, glucose control solutions, lancing device and lancets may be marketed within a single package (Kit), or available for purchase separately. Labeling included with the complete systems consist of an instruction booklet (Owner's Booklet), test strip insert, quick reference guide and logbook for recording test results. The meters support data transmission to a personal computer via a USB connection with the optional accessories of a micro USB cable for the TRUE METRIX GO and a docking station for the TRUE METRIX Self Monitoring Blood Glucose Systems.

B Principle of Operation:

The TRUE METRIX GO and TRUE METRIX Self Monitoring Blood Glucose Systems quantitatively measure blood glucose levels using an amperometric technology. The blood sample is drawn into the test strip by capillary action. The glucose in the sample interacts with the flavin adenine dinucleotide-glucose dehydrogenase (GDH-FAD) enzyme and the mediator in the test strip to produce an electrical current. The magnitude of the current is proportional to the concentration of glucose in the specimen. The electrical signal is converted into a readout on the meter displayed in plasma equivalents.

C Instrument Description Information:

1. Instrument Name:

   TRUE METRIX GO Self Monitoring Blood Glucose Meter
   TRUE METRIX Self Monitoring Blood Glucose Meter

2. Specimen Identification:

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

3. Specimen Sampling and Handling:

   The systems are intended to be used with capillary whole blood. The whole blood sample is applied directly to the test strip immediately upon collection.

4. Calibration:

   The systems are automatically coded and do not require calibration or coding by the user.

5. Quality Control:

   Three levels of aqueous glucose control solutions (Levels 1, 2 and 3) are available for use with these systems. Control solutions are sold separately. When a control solution is applied to the test strip, the meter automatically detects it as a control solution and displays a "Control Symbol". Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results. An 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.

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):

TRUE METRIX GO Self Monitoring Blood Glucose System

B Predicate 510(k) Number(s):

K143548

C Comparison with Predicate(s):

Device & Predicate Device(s):	K262873	K262873	K143548
Device Trade Name	TRUE METRIX GO Self Monitoring Blood Glucose System	TRUE METRIX Self Monitoring Blood Glucose System	TRUE METRIX GO Self Monitoring Blood Glucose System
General Device Characteristic Similarities			
Intended Use/ Indications For Use	Quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.	Same	Same
Measuring Range (mg/dL)	20 to 600	Same	Same

Device & Predicate Device(s):	K262873	K262873	K143548
General Device Characteristic Differences			
E-5 Error Message	Represents a test strip error	Represents a test strip error	Represents a test strip error, or very high blood glucose (>900 mg/dL)
EHi Error Message	Represents very high blood glucose (>900 mg/dL)	Represents very high blood glucose (>900 mg/dL)	N/A
Data Communication	micro USB	USB-enabled docking station	N/A

VI Standards/Guidance Documents Referenced:

CLSI EP06 2nd Edition - "Evaluation of Linearity of Quantitative Measurement Procedures"

FDA Guidance, "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use", September 29, 2020

FDA Guidance, "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions", February 3, 2026

VII Performance Characteristics (if/when applicable):

The device modifications described in this submission do not impact the glucose measurement functions of the system. Therefore, the performance data was leveraged from previously cleared devices (K143548 for the TRUE METRIX GO Self Monitoring Blood Glucose System; K140100 TRUE METRIX Self Monitoring Blood Glucose System)

A Analytical Performance:

1. Precision/Reproducibility:

   Previously established in K143548 and K140100.

2. Linearity:

   Previously established in K143548 and K140100.

3. Analytical Specificity/Interference:

   Previously established in K143548 and K140100.

   The sponsor includes the following information in the labeling:

- Ascorbic acid (Vitamin C) greater than normal or therapeutic levels may cause significant interference resulting in inaccurate results at concentrations greater than 2 mg/dL.
- Do not use during xylose absorption testing, as xylose may produce falsely elevated glucose results during a xylose absorption test for diagnostic evaluation of malabsorption. Please check with your doctor or healthcare professional before using the system.
- It is known that uric acid can interfere with this device at normal and disease levels, when uric acid concentrations are greater than 5 mg/dL. For people with diabetes, certain conditions may cause your blood level of uric acid to rise. These conditions include gout or kidney disease this means you may have significant interference resulting in inaccurate glucose results and your blood glucose results may be not reliable. Please check with doctor or healthcare professional before using the system.

4. Detection Limit and Assay Reportable Range:

   The assay reportable range is 20 to 600 mg/dL as previously established in K143548 and K140100.

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

   Traceability to the National Institute of Standards and Technology (NIST) SRM 917 glucose reference material, as previously established in K143548 and K140100.

   Test strip stability protocols and acceptance criteria were previously reviewed in K143548 and found acceptable to support the labeling claims that the test strips are stable for 4 months after first being opened, and closed vials are stable for 36 months when at the recommended storage temperatures 40º to 86 ºF (5 to 30ºC) and 10 to 80 % relative humidity. The labeling instructs the users not to freeze the test strips.

6. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See Section VII.C.3

2. Matrix Comparison:

   Not applicable. These devices are only intended for use with fresh capillary whole blood.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Clinical Cut-Off

   Not applicable.

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

   Previously established in K143548 and K140100.

D Expected Values/Reference Range:

The sponsor states the following in the labeling:

Expected Results for people without diabetes:

	Plasma Blood Glucose Result[1]
Before eating	< 100 mg/dL
2 hours after a meal	< 140 mg/dL

1. American Diabetes Association. *Diagnosis and Classification of Diabetes*: Diabetes Care 2026;49(Suppl. 1):S27–S49. https://doi.org/10.2337/dc26-S002

E Other Supportive Instrument Performance Characteristics Data:

Software and Cybersecurity
Software documentation was reviewed for reassignment of test strip error conditions caused by very high glucose levels (>900 mg/dL) from the "E-5" error code to the new "EHi" error code and found to be acceptable. Cybersecurity documentation was reviewed for the activation of data transfer function from the meters via a USB connection to a personal computer and found to be acceptable.

Hematocrit Study
Previously established in K143548 and K140100 to support the claimed hematocrit range of 20 to 70%

System Operating Conditions Study
Previously established in K143548 and K140100 to support the claims in the labeling that the system can be used in conditions of 41° to 104° F (5° to 40°C) with relative humidity of 10 to 90%.

Altitude Effects Study
Previously established in K143548 and K140100 to support the use of the device at altitudes up to 10,200 ft.

Sample Volume Study
Previously established in K143548 and K140100 to support the claimed minimum sample volume of 0.5 µL.

Electrical Safety and Electromagnetic Compatibility (EMC)
Previously established in K143548 and K120989.

Infection Control Testing
Previously established in K143548 and K120989. The device systems are intended for single patient use only. Disinfection efficacy studies were previously performed on the exterior meter materials demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant Super Sani-Cloth wipes (EPA Reg. No.: 9480-4). Robustness studies previously performed support 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

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.