July 23, 2026

Trividia Health, Inc.
Jacqueline Davis
Global Regulatory Affairs Product Manager
2400 NW 55th Ct.
Fort Lauderdale, Florida 33309

Re: K262116
Trade/Device Name: TRUE METRIX Self Monitoring Blood Glucose System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: June 23, 2026
Received: June 23, 2026

Dear Jacqueline Davis:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

PAULA V. CAPOSINO -S

Paula V. Caposino, Ph.D.
Deputy Director
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)*
K262116

Device Name
TRUE METRIX Self Monitoring Blood Glucose System

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

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.

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TRIVIDIA HEALTH
2400 N.W. 55TH COURT
FORT LAUDERDALE, FL 33309 U.S.A.

510(k) Summary

510(k) #: K262116 Date prepared: 7/22/2026

This 510(k) summary is submitted in accordance with 21 CFR 807.92.

Contact Details	
Applicant Name	Trividia Health, Inc.
Applicant Address	2400 N.W. 55th Court, Fort Lauderdale, FL 33309 United States
Applicant Contact Telephone	(800)342-7226
Applicant Contact	Jacqueline Davis
Applicant Contact Email	jdavis@trividiahealth.com
Device Name	
Device Trade Name	TRUE METRIX Self Monitoring Blood Glucose System
Common Name	Glucose test system
Classification Name	System, Test, Blood Glucose, Over The Counter
Regulation Number	21 CFR 862.1345
Product Code(s)	NBW
Legally Marketed Predicate Devices	
Predicate #	K140100
Predicate Trade Name	TRUE METRIX Self Monitoring Blood Glucose System
Product Code	NBW
Device Description Summary	
The TRUE METRIX Self Monitoring Blood Glucose System consists of the TRUE METRIX Self Monitoring Blood Glucose Meter and TRUE METRIX Self Monitoring Blood Glucose Test Strips. TRUE METRIX Control Solution, a lancing device, and lancets are required for use and are available separately or in various kit configurations.	

The TRUE METRIX Blood Glucose Test Strip is a disposable plastic strip containing reagents and electrodes. When inserted into a TRUE METRIX Meter, glucose is measured using amperometric technology based on a glucose dehydrogenase (GDH-FAD) reaction. Whole blood or TRUE METRIX Control Solution is applied to the sample area of the test strip, where glucose reacts with the strip reagents to generate an electrical current. The meter measures the current and calculates the glucose concentration, displaying the result as a plasma-equivalent glucose value.

Intended Use/Indications for Use

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

Indications for Use Comparison

The indications for use of the subject device are identical to those of the predicate device. Both devices are intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

Technological Comparison

The subject device has the same technological characteristics as the predicate device. Both devices have the same design, materials, operating principle, measurement principle, and energy source.

Description of Change:

The subject device incorporates a software modification that reassigns the error condition associated with very high glucose levels (>900 mg/dL) from the E-5 error code to the new EHi error code and includes corresponding labeling updates to reflect the revised error messaging and appropriate user actions.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Verification and validation testing included software verification and validation, system-level performance testing, and human factors/usability testing. The results demonstrated that the

modified device performs as intended and that users can correctly interpret and respond to the revised error messages. Clinical testing was not required because the modification does not affect glucose measurement performance, analytical accuracy, precision, or any other aspect of the device's analytical performance.

Based on the unchanged intended use and technological characteristics, and successful completion of verification and validation testing, the modified device does not raise new questions of safety or effectiveness. Therefore, the TRUE METRIX Self Monitoring Blood Glucose System is substantially equivalent to the predicate device.

Results of the verification and validation activities demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device.