December 19, 2025

Truvian Health
Tho Tran
Head of Quality Assurance & Regulatory Affairs
10300 Campus Point Dr., Suite 190
San Diego, CA 92121

Re: K251074
Trade/Device Name: Tru Liver Health Test Panel
Regulation Number: 21 CFR 862.1050
Regulation Name: Alkaline phosphatase or isoenzymes test system
Regulatory Class: Class II
Product Code: CJE, CIT, CKA
Dated: December 1, 2025
Received: December 1, 2025

Dear Tho Tran:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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 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)*
K251074

Device Name
Tru Liver Health Test Panel

Indications for Use *(Describe)*
The Tru Liver Health Test Panel is part of the TruWellness Panel™ and is intended for use on the Tru Analyzer. The Tru Liver Health Test Panel (part of the TruWellness Panel™) is an in vitro diagnostic device and intended to be used for the quantitative determination of Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST), and Alanine Aminotransferase (ALT) in lithium-heparinized venous whole blood in clinical laboratory or point-of-care settings.

The Tru Liver Health Test Panel (part of the TruWellness Panel™) is an in vitro diagnostic test system that aids the physician in diagnosing the following disorders in adults 18 years of age or older:

Alkaline Phosphatase (ALP): Liver, bone, parathyroid, and intestinal diseases.
Aspartate Aminotransferase (AST): Certain types of liver and heart diseases.
Alanine Aminotransferase (ALT): Certain liver (e.g., viral hepatitis and cirrhosis) and heart diseases.

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.

K251074 510(k) Summary

[In accordance with 21 CFR 807.92]

1 Submitter

Sponsor Name:	Truvian Health
Address:	10300 Campus Point Drive, Suite 190
	San Diego, CA 92121
Phone:	(760) 710-9712
Contact Person:	Tho Tran
Date Prepared:	December 19, 2025

2 Devices

Name of Devices: Tru Liver Health Test Panel

Classification Name	Regulation Number	Product Code / Class
Alkaline phosphatase or isoenzymes test system	862.1050	CJE / Class II
Aspartate amino transferase (AST/SGOT) test system	862.1100	CIT / Class II, 510(k) Exempt*
Alanine amino transferase (ALT/SGPT) test system	862.1030	CKA / Class I, 510(k) Exempt*

* Meets limitations of exemption per 21 CFR § 862.9 (c)(9)

3 Predicate Devices

Primary Predicate Devices: Skyla Comprehensive Metabolic Panel (K171971)

4 Device Description

The TruSystem is an automated, integrated *in vitro* diagnostic platform consisting of the Tru Analyzer and the Tru Liver Health Test Panel (part of the TruWellness Panel™), a Single-Use Consumable Kit that includes a Disc and a Support Pack. Designed for point-of-care and clinical laboratory use, the system enables the simultaneous measurement of clinical chemistry, immunoassay, and hematology parameters from a lithium-heparinized venous whole blood

sample in a single run. The TruSystem delivers quantitative results for routine clinical chemistry and immunoassay analytes as well as a complete blood count (CBC) with a 3-part differential, all without the need for specialized operating skills, external calibration, or complex infrastructure.

The Tru Analyzer is a benchtop instrument that fully automates sample processing, assay execution, and result reporting. Its touchscreen interface allows operators to control workflows, initiate tests, and review results with minimal training. The Single-Use Consumable Kit and blood sample are loaded into the analyzer drawer, where all necessary processing takes place. Internally, the Tru Analyzer integrates:

- A high precision pipettor for automated sample and reagent handling
- An onboard centrifuge to separate whole blood into plasma
- A closed-loop thermal control system to maintain precise assay temperatures
- A motion control system to fully automate sample processing
- Dedicated detection modules for clinical chemistry, immunoassay, and hematology testing
- A high-definition camera used to collect assay readings, image captures, and instrument quality control checks
- An electronics board to manage individual module boards and associated firmware
- An integrated computer running the instrument software, accessible via the touchscreen user interface

The Tru Analyzer is factory-calibrated and continuously monitors its performance using optical sensing and electronic feedback mechanisms. Every time the analyzer is powered on or a Single-Use Consumable Kit (TruWellness Panel™) is loaded, the system runs an automated self-test to verify that it remains within calibration and is functioning properly. Internal quality control (QC) checks occur throughout the testing process to ensure the integrity of the analyzer, Disc, and Support Pack.

If an internal QC check does not meet specifications, the instrument will automatically suppress result reporting to prevent the release of potentially inaccurate results. Any impacted tests will display associated codes in the footnotes of the patient report. The Tru Analyzer also applies result flags to highlight conditions that may indicate abnormalities in the patient sample or require attention. These flags appear in-line with impacted assay results for clear visibility. If a system operation failure occurs, the Tru Analyzer will halt the run, and no results will be generated. In these cases, the instrument displays an on-screen error message with a unique code and step-by-step instructions to guide resolution. These measures ensure the system provides accurate results, while requiring no special user knowledge, training, or on-site calibration.

The Single-Use Consumable Kit (TruWellness Panel™) houses all the components needed to process and analyze samples on the Tru Analyzer, including dried reagents, internal process control solutions, barcodes that manage the identity of the kit lot (e.g., Disc and Support Pack ID), calibration information, dilution buffers, and single-use plastic pipette tips. It also serves as a waste container which the user discards at the end of the run.

The Tru Liver Health Test Panel is part of the TruWellness Panel™ and is intended for use on the Tru Analyzer. The Tru Liver Health Test Panel (part of the TruWellness Panel™) provides *in vitro* quantitative determination of Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST), and Alanine Aminotransferase (ALT) in lithium-heparinized venous whole blood samples.

5 Indications for Use

The Tru Liver Health Test Panel is part of the TruWellness Panel™ and is intended for use on the Tru Analyzer. The Tru Liver Health Test Panel (part of the TruWellness Panel™) is an in vitro diagnostic device and intended to be used for the quantitative determination of Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST), and Alanine Aminotransferase (ALT) in lithium-heparinized venous whole blood in clinical laboratory or point-of-care settings.

The Tru Liver Health Test Panel (part of the TruWellness Panel™) is an in vitro diagnostic test system that aids the physician in diagnosing the following disorders in adults 18 years of age or older:

- Alkaline Phosphatase (ALP): Liver, bone, parathyroid, and intestinal diseases.
- Aspartate Aminotransferase (AST): Certain types of liver and heart diseases.
- Alanine Aminotransferase (ALT): Certain liver (e.g., viral hepatitis and cirrhosis) and heart diseases.

6 Comparison of Technological Characteristics with the Predicate Device

The tables below compare the similarities and differences between the technological characteristics of the Tru Liver Health Test Panel (part of the TruWellness Panel™) and Tru Analyzer to the legally marketed predicate devices.

Substantial equivalence was demonstrated through performance testing for the following performance characteristics: precision / reproducibility, linearity, detection limits, interferences, assay measuring ranges, reference ranges, and method comparison. Performance data for the subject device shows comparable results to the predicate device.

Table 1. Tru Liver Health Test Panel (Part of the TruWellness Panel™) Comparison Chart

Characteristic	Subject Device Tru Liver Health Test Panel (part of the TruWellness Panel™)	Predicate Device K171971
Intended Use	*In vitro* quantitative determination of Alkaline phosphatase (ALP), Aspartate aminotransferase (AST), and Alanine aminotransferase (ALT) concentrations in lithium-heparinized venous whole blood in clinical laboratory or point-of-care settings.	*In vitro* quantitative determination of alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), blood urea nitrogen (BUN) and creatinine (CRE) concentrations in lithium-heparinized venous whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.
Intended Use Setting	Clinical laboratory or point-of-care setting	Same
Specimen Type	Lithium-heparinized venous whole blood	Lithium-heparinized venous whole blood or plasma and serum
Detection Wavelengths	ALP: 405 nm AST: 340 nm ALT: 340 nm	Same
Calibration	Barcode on each reagent disc with factory-calibrated lot-specific data	Same
Reagent Storage	2-8°C (36-45°F) or 15-25°C (59-77°F) for up to 14 days	2-8°C (36-45°F)
Analytical Measuring Ranges	ALP: 25 – 1200 U/L AST: 11 – 700 U/L ALT: 15 – 500 U/L	ALP: 41 – 1500 U/L ALT: 20 – 500 U/L AST: 20 – 1000 U/L

7 Recognized Consensus Standards

The following recognized consensus standards were used as a basis for analytical performance testing:

- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition
- CLSI EP06 Ed.2, Evaluation of the Linearity of Quantitative Measurement Procedures
- CLSI EP07 Ed.3, Interference Testing in Clinical Chemistry
- CLSI EP09c Ed.3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline–Second Edition
- CLSI EP25 Ed.2, Evaluation of Stability of In Vitro Medical Laboratory Test Reagents
- CLSI EP28-A3c, Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition
- CLSI EP37 Ed.1, Supplemental Tables for Interference Testing in Clinical Chemistry

8 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

8.1 Precision / Reproducibility

Precision studies were performed in accordance with CLSI document EP05-A3. The total precision (reproducibility), as well as within-run, between-day, and between-site precision, was assessed by testing three levels of control samples (low, medium, and high) across three sites. At least three operators performed testing per site, and each site utilized three Tru Analyzers. Each site performed a minimum of 90 valid replicates for each control level over a 5-day period (2 runs per day, 3 replicates per run) on one lot of Single-Use Consumable Kits. Summary results are provided in the table below.

Analyte	Level	N	Mean	Within-Run		Between-Run		Between-Day		Between-Site		Total Precision*	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
ALP (U/L)	Low	91	71	4	4.9	0	0.0	1	1.4	1	1.9	4	5.5
ALP (U/L)	Med	91	120	6	4.6	0	0.0	2	1.2	1	0.9	6	4.9
ALP (U/L)	High	92	373	8	2.2	2	0.5	0	0.0	7	1.9	11	2.9
AST (U/L)	Low	92	57	1	1.9	0.3	0.4	0.4	0.7	2	3.6	2	4.1
AST (U/L)	Med	91	292	6	2.0	0	0.0	3	1.0	4	1.4	8	2.7
AST (U/L)	High	92	508	7	1.3	3	0.7	4	0.7	5	1.1	10	2.0
ALT (U/L)	Low	92	62	2	2.9	1	1.1	0	0.0	2	3.2	3	4.5
ALT (U/L)	Med	91	291	6	1.9	0	0.0	3	0.9	3	1.1	7	2.4

Analyte	Level	N	Mean	Within-Run		Between-Run		Between-Day		Between-Site		Total Precision*	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
ALT (U/L)	High	92	427	5	1.1	2	0.5	3	0.6	4	1.0	7	1.7

* Total Precision represents reproducibility, which is the sum of all variance components.

8.1.1 Whole Blood Precision

Whole blood precision was evaluated using Li-Hep whole blood samples collected across five sites from the intended use population with normal and abnormal blood chemistry analyte levels. For each test subject, eight replicates were measured across four instruments and two operators. The SD and CV% were calculated per subject. These variances were pooled across subjects for the defined analyte ranges and summarized in the table below.

Analyte	Range	N	Median	SD	CV%
ALP (U/L)	25–130	66	79	4.3	5.8
ALP (U/L)	130–300	16	200	5.9	3.1
ALP (U/L)	300–1,200	7	584	20.4	4.2
AST (U/L)	11–30	57	18	1.2	6.7
AST (U/L)	30–100	22	39	1.5	3.5
AST (U/L)	100–700	7	139	5.0	3.6
ALT (U/L)	15–30	39	20	1.4	6.5
ALT (U/L)	30–100	23	44	1.8	3.9
ALT (U/L)	100–500	7	205	9.9	4.4

8.2 Linearity

Linearity testing was performed in accordance with CLSI document EP06-Ed2. Whole blood-based linearity panels, consisting of numerous sample levels including at least one sample level below the assay lower limit linearity interval and one sample level above the assay upper limit linearity interval, were tested across multiple instruments and kit lots.

Summary results are provided in the table below.

Analyte	Tested Linear Range	Claimed Linear Range
ALP (U/L)	5 – 1,464	25 – 1,200
AST (U/L)	3 – 865	11 – 700
ALT (U/L)	8 – 618	15 – 500

8.3 Detection Limits

Detection limits were determined in accordance with CLSI document EP17-A2. The Limit of Blank (LoB) corresponds to the highest measurement result that is likely to be observed for a blank sample. The assay is designed to have a LoB ≤ Limit of Detection (LoD).

The Limit of Detection (LoD) corresponds to the lowest concentration of analyte that can be detected with a probability of 95%. The assay is designed to have an LoD ≤ Limit of Quantitation (LoQ).

The Limit of Quantitation (LoQ) corresponds to the lowest concentration of analyte in a sample that had a CV ≤ 20%. Detection limits are provided in the table below.

LoD and LoQ were established in Li-Hep whole blood samples.

Analyte	LoB	LoD	LoQ
ALP (U/L)	6.15	12	22
AST (U/L)	2.29	4	11
ALT (U/L)	5.80	8	11

8.4 Analytical Measuring Range

The analytical measuring range (AMR) was established based on the LoQ and the linear range data of each analyte. The Tru Analyzer will report results within the AMR as listed in the table below.

Analyte	AMR
ALP (U/L)	25 – 1,200
AST (U/L)	11 – 700
ALT (U/L)	15 – 500

8.5 Reference Range / Expected Values

The reference ranges were established based on scientific literature[1]. The normal (“healthy”) values for ALP, AST, and ALT are listed below. These ranges in the table below are provided as guidelines only.

Analyte		Reference Range
ALP (U/L)		37 – 108
AST (U/L)	Male	< 35
	Female	< 31
ALT (U/L)	Male	< 45
	Female	< 34

[1] C. A. Burtis, E. R. Ashwood, and D. E. Bruns. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 4th ed., Elsevier Saunders, St. Louis, (2006).

8.6 Interferences

Following CLSI documents EP07 and EP37, endogenous and exogenous substances were spiked into samples to assess potential interference. All testing was performed using contrived whole blood samples at two targeted analyte concentration levels. Interference is defined as the analyte result shifted by more than 10% or by a fixed value consistent with CLSI EP07 section 3.1.2, whichever is greater. Summary results are provided in the tables below.

Summary of Endogenous Substances

Substance	Max Concentration without Interference			
	ALP	AST	ALT	Units
Lipemia (Triglycerides)	1,037	1,037	1,037	mg/dL
Hemolysis (Hemoglobin)	48	159	545	mg/dL
Conjugated Bilirubin	22.5	22.5	22.5	mg/dL
Unconjugated Bilirubin	31.5	14.0	27.5	mg/dL

Summary of Exogenous Substances

Substance	Max Concentration without Interference			
	ALP	AST	ALT	Units
Acetaminophen	15.6	15.6	15.6	mg/dL
Acetylsalicylic acid	3.0	3.0	3.0	mg/dL
Ampicillin	7.5	7.5	7.5	mg/dL

Substance	Max Concentration without Interference			
	ALP	AST	ALT	Units
Cefoxitin	330	660	495	mg/dL
Cyclosporine	0.18	0.18	0.18	mg/dL
Doxycycline	1.35	1.8	1.8	mg/dL
Heparin	3,300	3,300	3,300	U/L
Ibuprofen	21.9	21.9	21.9	mg/dL
Levodopa (L-Dopa)	0.75	0.75	0.75	mg/dL
Methyldopa	2.25	2.25	2.25	mg/dL
Metronidazole	12.3	12.3	12.3	mg/dL
Phenylbutazone	24.1	32.1	32.1	mg/dL
Rifampicin	4.8	4.8	4.8	mg/dL
Theophylline	6.0	6.0	6.0	mg/dL
Acetylcysteine	15	15	15	mg/dL
Ascorbic Acid	5.25	5.25	5.25	mg/dL
Caffeine	8.1	10.8	10.8	mg/dL
Cephalothin	135	135	180	mg/dL
Cimetidine	3.0	3.0	3.0	mg/dL
Salicylic Acid	2.86	2.86	2.86	mg/dL

8.7 Traceability

The assay calibrators are traceable to the reference materials in the table below. The calibration parameters for each analyte are established internally. The calibration information is barcoded on each Single-Use Consumable Kit.

Assay	Traceable Material
ALP	CRM001d + water blank
AST	IFCC method→Roche Cobas
ALT	IFCC method→Roche Cobas

8.8 Method Comparison Study

Whole blood specimens were prospectively collected from subjects at five external sites. For each subject, two Li-Hep (no gel) tubes of whole blood and one EDTA tube were collected. One Li-Hep tube was analyzed on the Tru Analyzer, while the other was centrifuged shortly after collection to obtain Li-Hep plasma. The Li-Hep plasma and the EDTA sample were then shipped to a central

laboratory for analysis using FDA-cleared comparator methods. Additionally, contrived samples were used sparingly to address extremely rare high and low target analytes. Truvian results were compared with results from the Roche Cobas Chemistry (c module) analyzer. Summary results are provided in the table below.

Analyte	Units	N	Range	Slope	Intercept	R
ALP	U/L	259	30–1,185	1.04	-3.06	0.997
AST	U/L	272	11–673	1.00	1.00	0.999
ALT	U/L	193	15 – 464	0.91	2.62	0.999

8.9 EMC and Safety

The Tru Analyzer has been tested and complies with the following internationally recognized consensus standards for electromagnetic compatibility and safety:

- IEC 61326-2-6: 2020
- IEC 61326-1: 2020
- ETSI EN 301 489-1 V2.2.3 (2019-11)
- ETSI EN 301 489-17 V3.2.4 (2020-09)
- CFR47 FCC Part 15, Subpart B (Class A)
- ICES-003 Issue 7 October 2020
- CFR47 FCC Part 15, Subpart C, 15.247
- RSS-Gen – Issue 5, April 2018 including Amendment 1 (March 2019) and Amendment 2 (February 2021)
- ETSI EN 300 328 V2.2.2. (2019-07)
- ETSI EN 301 893 V2.1.1 (2017-05)

9 Conclusions

The performance data confirms that the subject device performs as intended and is as safe and effective as the predicate devices. Thus, the equivalence assessment and performance data demonstrate substantial equivalence to the predicates in terms of safety and effectiveness.