January 16, 2026

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

Re: K251249
Trade/Device Name: Tru Hematology Test
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: December 15, 2025
Received: December 16, 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,

Ying Mao -S

for

Takeesha Taylor-Bell
Deputy Director
Division of Immunology and Hematology 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)*
K251249

Device Name
Tru Hematology Test

Indications for Use *(Describe)*
The Tru Hematology Test is part of the TruWellness Panel™ and is intended for use on the Tru Analyzer. The Tru Hematology Test (part of the TruWellness Panel™) is an in vitro diagnostic device and intended to classify and enumerate WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, Lymph#, Lymph%, Neut#, Neut%, Other WBC#, and Other WBC% in lithium-heparinized venous whole blood in clinical laboratory or point-of-care settings.

The Tru Hematology Test (part of the TruWellness Panel™) is intended for use in adults 18 years of age or older. It is not intended for use in diagnosing or monitoring critical disease states such as oncology.

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.

K251249 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:	January 16, 2026

2 Devices

Name of Devices: Tru Hematology Test

Classification Name	Regulation Number	Product Code / Class
Automated differential cell counter	864.5220	GKZ / Class 2

3 Predicate Devices

Predicate Device Sight OLO (K190898)

4 Device Description

The TruSystem is an automated, integrated in vitro diagnostic platform consisting of the Tru Analyzer and 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 capture, 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 any self-test or QC check fails to meet system specifications, the Tru Analyzer will display an error code and next steps on the touchscreen interface.

The Single-Use Consumable Kit (TruWellness Panel™) houses all the components needed to process as well as 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 of at the end of the run.

The Tru Hematology Test is part of the TruWellness Panel™ and is intended for use on the Tru Analyzer. The Tru Hematology Test is an in-vitro diagnostic device intended to classify and enumerate WBC, Lymph # and %, Neut # and %, Other WBC # and %**,** RBC, HGB, HCT, MCH, MCHC, MCV, and PLT in lithium-heparinized venous whole blood samples.

5 Indications for Use

The Tru Hematology Test is part of the TruWellness Panel™ and is intended for use on the Tru Analyzer. The Tru Hematology Test (part of the TruWellness Panel™) is an in vitro diagnostic device and intended to classify and enumerate WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, Lymph#, Lymph%, Neut#, Neut%, Other WBC#, and Other WBC% in lithium-heparinized venous whole blood in clinical laboratory or point-of-care settings.

The Tru Hematology Test (part of the TruWellness Panel™) is intended for use in adults 18 years of age or older. It is not intended for use in diagnosing or monitoring critical disease states such as oncology.

6 Comparison of Technological Characteristics with the Predicate Device

The tables below compare the similarities and differences between the technological characteristics of the Tru Hematology Test and Tru Analyzer to the legally marketed predicate device.

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 acceptable results compared to the predicate device.

Table 1. Tru Hematology Test Comparison Chart

Characteristic	Subject Device Tru Hematology Test	Primary Predicate Device K190898
Analytes	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT#, NEUT%, LYMPH#, LYMPH%, Other WBC#, and Other WBC%.	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT#, NEUT%, LYMPH#, LYMPH%, MONO#, MONO%, EOS#, EOS%, BASO#, and BASO%.
Product Code / Regulation	GKZ / 864.5220	Same
Intended Use	In vitro diagnostic device and is intended to classify and enumerate WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, Lymph#, Lymph%, Neut#, Neut%, Other WBC#, and Other WBC% in lithium-heparinized venous whole blood in clinical laboratory or point-of-care settings. It is intended for use in adults 18 years of age or older. It is not intended for use in diagnosing or monitoring critical disease states such as oncology.	In vitro diagnostic use in screening capillary or venous whole blood samples collected in K2EDTA blood collection tubes, or fingertip samples collected using the Sight OLO test kit micro-capillary tubes. When used with the Sight OLO cartridge, the Sight OLO enumerates the following CBC parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH %/#, MONO %/#, EOS%/#, and BASO%/#.The Sight OLO is indicated for use in clinical laboratories to identify and classify one or more of the formed elements of blood in children 3 months and above, adolescents and adults.
Intended Use Setting	Clinical laboratory or point-of-care setting for professional use	Clinical laboratory

Characteristic	Subject Device Tru Hematology Test	Primary Predicate Device K190898
Specimen Type	Venous whole blood	Whole blood (venous and capillary)
Anticoagulant Type	Lithium heparin	K2-EDTA
Assay Principle	HGB: cyanmethemoglobin method HCT: microhematocrit centrifugation All other test parameters: computer vision-based blood analysis with brightfield and fluorescence microscopy	HGB: Optical density measurement HCT: computer vision-based blood analysis with brightfield and fluorescence microscopy All other test parameters: computer vision-based blood analysis with brightfield and fluorescence microscopy
Detection Method	HGB: Photometric / Colorimetric method HCT: Image analysis All other test parameters: Image analysis	Same
Reagent Storage	2-8°C (36-45°F) 15-25°C (59-77°F) for up to 14 days	18-26°C (64-79°F)
Analytical Measuring Range	WBC: 1.0 – 100.0 K/µL RBC: 1.00 – 7.50 M/µL HGB: 4.0 – 22.0 g/dL HCT: 15.0 – 60.0 % PLT: 15 – 1,000 K/µL LYMPH#: 0.0 – 100.0 K/µL NEUT#: 0.0 – 100.0 K/µL Other WBC#: 0.0 – 100.0 K/µL	WBC: 0.18 – 100.13 K/µL RBC: 1.22 – 7.55 M/µL HGB: 4.0 – 21.75 g/dL HCT: 15.2 – 63.7 % PLT: 15.0 – 1000 K/µL LYMPH#: 0.0 – 100 K/µL NEUT#: 0.0 – 100 K/µL MONO#: 0.0 – 100 K/µL EOS#: 0.0 – 100 K/µL BASO#: 0.0 – 100 K/µL

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
- CLSI H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard - Second Edition
- CLSI GP41 Ed.7, Collection of Diagnostic Venous Blood Specimens

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.

Analyte	Level	n	Mean	Within-Run		Between-Run		Between-Day		Between-Site		Total*	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
WBC ($x\ 10^3/\mu L$)	Low	90	2.6	0.1	5.3	0.0	1.3	0.0	0.0	0.0	0.3	0.1	5.5
	Med	90	7.9	0.2	2.8	0.0	0.0	0.0	0.0	0.2	2.2	0.3	3.6
	High	90	17.2	0.4	2.2	0.0	0.0	0.1	0.7	0.2	1.3	0.4	2.6
RBC ($x\ 10^6/\mu L$)	Low	90	2.15	0.04	1.7	0.01	0.6	0.00	0.1	0.00	0.0	0.04	1.8
	Med	90	4.18	0.05	1.2	0.01	0.3	0.00	0.0	0.06	1.5	0.08	2.0
	High	90	6.05	0.09	1.5	0.02	0.3	0.00	0.0	0.06	0.9	0.11	1.8

Analyte	Level	n	Mean	Within-Run		Between-Run		Between-Day		Between-Site		Total*	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Hemoglobin (g/dL)	Low	90	6.3	0.2	2.6	0.0	0.0	0.0	0.6	0.1	1.5	0.2	3.1
	Med	90	13.2	0.2	1.9	0.0	0.1	0.0	0.3	0.2	1.3	0.3	2.3
	High	90	19.1	0.5	2.4	0.0	0.0	0.0	0.2	0.1	0.6	0.5	2.4
Hematocrit (%)	Low	90	17.2	0.2	1.3	0.0	0.0	0.1	0.5	0.0	0.1	0.2	1.4
	Med	90	35.7	0.3	0.8	0.0	0.0	0.1	0.4	0.0	0.0	0.3	0.9
	High	90	53.5	0.4	0.7	0.1	0.2	0.1	0.1	0.0	0.1	0.4	0.8
MCV (fL)	Low	90	80	2	2.0	1	0.6	0	0.0	0	0.0	2	2.1
	Med	90	85	1	1.5	0	0.2	0	0.0	1	1.3	2	2.0
	High	90	88	1	1.5	0	0.0	0	0.5	1	1.1	2	1.9
MCH (pg)	Low	90	29.2	1.0	3.4	0.0	0.0	0.1	0.2	0.5	1.7	1.1	3.8
	Med	90	31.5	0.7	2.2	0.3	0.9	0.1	0.3	0.0	0.0	0.8	2.4
	High	90	31.6	0.8	2.6	0.0	0.0	0.0	0.0	0.0	0.0	0.8	2.6
MCHC (g/dL)	Low	90	36.4	1.1	3.0	0.0	0.0	0.0	0.0	0.7	1.9	1.3	3.6
	Med	90	37.0	0.8	2.1	0.0	0.0	0.2	0.5	0.4	1.1	0.9	2.4
	High	90	35.7	0.8	2.4	0.0	0.0	0.0	0.0	0.3	0.8	0.9	2.5
Platelets (x 10^3/µL)	Low	90	78	2	3.2	0	0.0	0	0.0	1	1.2	3	3.4
	Med	90	251	5	1.8	0	0.0	0	0.0	7	2.9	9	3.4
	High	90	588	10	1.7	0	0.0	0	0.0	13	2.1	16	2.7
Neutrophils (%)	Low	90	35.8	2.6	7.3	1.4	3.8	0.0	0.0	2.1	5.9	3.6	10.2
	Med	90	56.6	1.7	3.1	0.0	0.0	0.0	0.0	1.0	1.8	2.0	3.6
	High	90	75.1	1.3	1.7	0.0	0.0	0.0	0.0	0.0	0.0	1.3	1.7
Lymphocytes (%)	Low	90	33.5	2.6	7.9	0.0	0.0	0.0	0.0	1.6	4.7	3.1	9.1
	Med	90	31.8	1.6	4.9	0.0	0.0	0.0	0.0	1.7	5.3	2.3	7.2
	High	90	16.7	1.1	6.6	0.0	0.0	0.0	0.0	0.3	1.9	1.2	6.9
Other (%)	Low	90	30.7	2.1	7.0	0.9	2.8	0.0	0.0	0.4	1.3	2.3	7.6
	Med	90	11.6	0.8	7.1	0.0	0.0	0.0	0.0	0.7	5.8	1.1	9.2
	High	90	8.1	0.6	7.5	0.3	3.6	0.0	0.0	0.3	4.3	0.8	9.4
Neutrophils (Absolute) (x 10^3/µL)	Low	90	0.9	0.1	9.6	0.0	3.7	0.0	0.0	0.1	6.8	0.1	12.3
	Med	90	4.5	0.2	3.8	0.0	0.0	0.0	0.0	0.0	0.0	0.2	3.8
	High	90	12.9	0.4	2.7	0.1	0.5	0.0	0.0	0.2	1.4	0.4	3.1
Lymphocytes (Absolute) (x 10^3/µL)	Low	90	0.9	0.1	9.9	0.0	0.0	0.0	0.0	0.0	3.4	0.1	10.4
	Med	90	2.5	0.2	6.0	0.0	0.0	0.0	0.0	0.2	7.5	0.2	9.6
	High	90	2.9	0.2	7.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	7.0

Analyte	Level	n	Mean	Within-Run		Between-Run		Between-Day		Between-Site		Total*	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Other (Absolute) (x 10^3/µL)	Low	90	0.8	0.1	7.6	0.0	3.7	0.0	0.0	0.0	0.0	0.1	8.5
	Med	90	0.9	0.1	7.9	0.0	0.0	0.0	1.5	0.0	3.7	0.1	8.8
	High	90	1.4	0.1	8.1	0.1	3.6	0.0	1.5	0.1	5.3	0.1	10.4

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

8.1.1 Whole Blood Precision

Whole blood precision was evaluated using specimens collected across five sites from the intended-use population with normal and abnormal 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	Subject (n)	Replicate (n)	Mean	SD	CV%
RBC (x 10^6/µL)	1.00–4.00	53	412	3.46	0.108	3.0%
RBC (x 10^6/µL)	4.00–6.50	70	536	4.66	0.135	2.8%
RBC (x 10^6/µL)	6.50–7.50	1	8	6.50	0.162	2.5%
WBC (x 10^3/µL)	1.0–4.0	10	76	3.5	0.18	5.3%
WBC (x 10^3/µL)	4.0–10.0	76	590	6.7	0.25	3.7%
WBC (x 10^3/µL)	10.0–100.0	37	282	16.1	0.49	3.4%
Hemoglobin (g/dL)	4.0–11.5	51	400	10.0	0.297	2.9%
Hemoglobin (g/dL)	11.5–15.5	65	503	13.4	0.354	2.7%
Hemoglobin (g/dL)	15.5–22.0	8	62	16.7	0.348	2.1%
Hematocrit (%)	15.0–30.0	15	112	25.9	0.462	1.9%
Hematocrit (%)	30.0–50.0	100	770	38.2	0.703	1.9%
Hematocrit (%)	50.0–60.0	2	16	52.7	0.378	0.7%
MCV (fL)	74–86	32	249	82	2.420	3.0%
MCV (fL)	86–90	40	306	88	2.438	2.8%
MCV (fL)	90–106	45	343	96	2.607	2.7%
MCH (pg)	21.0–28.0	30	232	26.2	0.887	3.4%
MCH (pg)	28.0–30.0	44	341	29.1	0.839	2.9%

Analyte	Range	Subject (n)	Replicate (n)	Mean	SD	CV%
MCH (pg)	30.0–36.0	50	383	31.7	0.922	2.9%
MCHC (g/dL)	28.0–32.0	34	258	31.1	0.899	2.9%
MCHC (g/dL)	32.0–33.0	24	186	32.6	0.876	2.7%
MCHC (g/dL)	33.0–38.0	59	454	34.2	0.884	2.6%
Platelets (x 10^3/µL)	10–125	18	129	88	4.75	6.6%
Platelets (x 10^3/µL)	125–500	99	763	264	13.40	4.6%
Platelets (x 10^3/µL)	500–1,000	6	45	715	27.98	4.1%
Lymphocytes (%)	2.0–12.0	40	299	7.5	0.648	8.8%
Lymphocytes (%)	12.0–23.0	41	322	17.7	1.207	7.0%
Lymphocytes (%)	23.0–59.0	42	326	34.3	1.662	5.1%
Neutrophils (%)	24.0–62.0	37	288	51.1	2.073	4.4%
Neutrophils (%)	62.0–74.0	43	335	68.2	1.686	2.5%
Neutrophils (%)	74.0–91.0	43	324	81.4	1.468	1.8%
Other (%)	2.0–9.0	34	264	7.5	0.902	12.6%
Other (%)	9.0–12.0	38	290	10.3	1.210	11.8%
Other (%)	12.0–54.0	51	393	17.0	1.542	9.3%
Neutrophils (Absolute) (x 10^3/µL)	0.0–1.5	2	15	1.1	0.11	10.4%
Neutrophils (Absolute) (x 10^3/µL)	1.5–7.0	83	645	4.1	0.21	5.5%
Neutrophils (Absolute) (x 10^3/µL)	7.0–100.0	38	287	11.6	0.55	4.2%
Lymphocytes (Absolute) (x 10^3/µL)	0.0–1.0	42	311	0.7	0.07	11.3%
Lymphocytes (Absolute) (x 10^3/µL)	1.0–3.0	76	596	1.8	0.11	6.4%
Lymphocytes (Absolute) (x 10^3/µL)	3.0–5.0	4	32	3.9	0.22	5.6%
Other (Absolute) (x 10^3/µL)	0.0–1.5	99	762	0.8	0.093	12.8%
Other (Absolute) (x 10^3/µL)	1.5–3.0	21	166	1.9	0.197	10.6%
Other (Absolute) (x 10^3/µL)	3.0–5.0	2	11	3.2	0.318	10.1%

8.2 Linearity

Linearity testing was performed in accordance with CLSI document EP06-Ed2. Hematology linearity panels consisted 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. Samples were tested across multiple instruments and linearity was evaluated by analyzing data against assay specific acceptance criteria.

Analyte	Tested Linear Range	Claimed Linear Range	Units
WBC	0.5–120.0	1.0–100.0	x 10^3/µL
RBC	0.54–7.89	1.00–7.50	x 10^6/µL
Hemoglobin	3.0–22.8	4.0–22.0	g/dL
Hematocrit	12.7–71.4	15.0–60.0	%
Platelets	8–1,152	15–1,000	x 10^3/µL

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.

Analyte	LoB	LoD	LoQ	Units
WBC	0.1	0.2	0.2	x 10^3/µL
RBC	N/A	0.22	0.30	x 10^6/µL
Hemoglobin	0.2	0.3	0.4	g/dL
HCT	N/A	0.9	2.0	%
Platelets	7	9	15	x 10^3/µL

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	Units
WBC	1.0–100.0	x 10^3/µL

RBC	1.00–7.50	x 10^6/µL
Hemoglobin	4.0–22.0	g/dL
Hematocrit	15.0–60.0	%
Platelets	15–1,000	x 10^3/µL
Neutrophils (Absolute)	0.0–100.0	x 10^3/µL
Lymphocytes (Absolute)	0.0–100.0	x 10^3/µL
Other (Absolute)	0.0–100.0	x 10^3/µL

8.5 Reference Range / Expected Values

The reference interval was established according to CLSI guideline EP28-A3c section 9.4.2. In total, 256 unique adult subjects (128 male and 128 female subjects) provided Li-Hep venous whole blood specimens to be tested on the Tru Analyzer. All subjects were 18 years of age or older and self-reported to have no signs or symptoms of acute or chronic diseases, with normal findings in previous clinical assessments, laboratory tests, and medical history.

These ranges are provided as guidelines only. It is recommended that your office or institution establish its own normal ranges for the specific patient population.

Analyte	Reference Interval			Units
	All	Female	Male	
WBC	3.5–10.0	3.9–10.2	3.4–10.1	x 10^3/µL
RBC	3.90–5.43	3.85–5.33	4.14–5.46	x 10^6/µL
Hemoglobin	11.1–16.1	10.6–15.0	12.2–16.3	g/dL
Hematocrit	35.1–46.7	33.9–44.5	37.9–46.9	%
MCV	78–97	77–97	81–96	fL
MCH	25.4–33.2	23.6–34.0	27.1–32.8	pg
MCHC	31.4–36.2	31.1–36.4	31.6–36.1	g/dL
Platelets	148–393	174–401	141–388	x 10^3/µL
Neutrophils	40.6–73.4	40.5–73.4	40.5–75.6	%
Lymphocytes	19.3–46.2	19.9–46.6	17.4–45.7	%
Other	6.0–17.1	5.5–16.7	7.1–17.3	%
Neutrophils (Absolute)	1.8–7.4	1.8–7.6	1.7–7.0	x 10^3/µL
Lymphocytes (Absolute)	1.1–3.3	1.1–3.3	1.1–3.1	x 10^3/µL
Other (Absolute)	0.4–1.1	0.4–1.0	0.4–1.2	x 10^3/µL

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.

Substance	Max Concentration without Interference					
	WBC	RBC	Hemoglobin	Hematocrit	Platelets	Units
Lipemia (Intralipid)	1,363.7	1,818.2	1,818.2	454.6	1,363.7	mg/dL
Hemolysis (Hemoglobin)	476.2	714.3	N/A	476.2	119.1	mg/dL
Hemolysis (Cell Lysis)	N/A	N/A	No Interference	N/A	N/A	N/A

Substance	Max Concentration without Interference					
	WBC	RBC	Hemoglobin	Hematocrit	Platelets	Units
Icterus (Conjugated Bilirubin)	38.1	38.1	38.1	19.1	38.1	mg/dL
Icterus (Unconjugated Bilirubin)	28.6	38.1	38.1	9.5	28.6	mg/dL
D-Glucose	952.4	952.4	952.4	952.4	952.4	mg/dL
Chylomicrons	440.6	440.6	440.6	440.6	55.1	mg/dL
Yeast	4.8	4.8	4.8	4.8	4.8	mg/dL
PLT Aggregates	Interference Observed	No Interference	No Interference	No Interference	Interference Observed	N/A

8.7 Traceability

The hematology assays, including WBC, Neut, Lym, Others, RBC, HCT, and PLT, require static calibration factors that are incorporated into the instrument panel software to generate final reported values. These calibration factors were empirically derived during development to maximize concordance with the comparator hematology analyzer Sysmex XN. They are independent of the consumable lots and are only specific to the panel version. The HGB assay is the only hematology assay that uses the consumable-specific calibration coefficients that are consumable lot-specific.

The HGB assay calibrators are traceable to the reference materials in the table below. The calibration parameters for HGB are established internally and the assigned values for calibrators are unique for each reagent lot. The calibration information is barcoded on each Single-Use Consumable Kit.

Assay	Traceable Material
HGB	JCCRM 912-3 (3-levels)

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 Sysmex XN hematology analyzer.

Analyte	Units	N	Range	Slope	Intercept	R
WBC	x 10^3/µL	383	1.2–91.4	0.96	0.04	0.993
RBC	x 10^6/µL	392	1.83–6.97	0.94	0.22	0.971
Hemoglobin	g/dL	399	4.0–20.7	0.95	0.67	0.973
Hematocrit	%	373	17.2–57.9	0.96	1.14	0.975
MCV	fL	373	71–114	1.04	-3.11	0.826
MCH	pg	391	16.5–41.2	1.00	0.50	0.887
MCHC	g/dL	372	16.4–40.3	1.56	-17.76	0.555
Platelets	x 10^3/µL	370	14–996	0.94	5.09	0.966
Neutrophils	%	274	0.5–94.4	0.99	-0.05	0.971
Lymphocytes	%	274	0.4–81.2	1.00	0.30	0.987
Other	%	274	0.7–32.1	0.92	0.91	0.702
Neutrophils (Absolute)	x 10^3/µL	274	0.0–15.4	0.96	-0.04	0.975
Lymphocytes (Absolute)	x 10^3/µL	274	0.0–40.2	0.94	0.04	0.996
Other (Absolute)	x 10^3/µL	274	0.1–11.1	0.78	0.13	0.870

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 confirm 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.