April 27, 2026

Diagnostica Stago, Inc.
Louise Sigismondi
Director-US Market Access
Five Century Dr., Suite 200.
Parsippany, New Jersey 07054

Re: K253658
Trade/Device Name: STA Satellite Max
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: JPA
Dated: November 19, 2025
Received: November 20, 2025

Dear Louise Sigismondi:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

Takeesha Taylor-Bell

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)*
K253658

Device Name
STA Satellite Max®

Indications for Use *(Describe)*
The STA Satellite Max® is a fully automatic clinical analyzer intended to be used by professional laboratory personnel for qualitative and/or quantitative in vitro determination and to perform clotting, chromogenic and immunoassay tests on human venous plasmas (3.2% citrate) the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

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.

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510(k) SUMMARY

This 510(k) summary of safety and effectiveness is submitted in accordance with the requirements of 21 CFR 807.92 and follows FDA guidance 'The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]', issued July 28, 2014.

1. Applicant

Diagnostica Stago, Inc.
5 Century Drive
Parsippany, NJ 07054
Louise M. Sigismondi, Ph.D.
Director, US Market Access
Phone: +1 973-631-1200 x4162

2. Device

510(k):	K253658
Device Name:	STA Satellite Max®
Common Name:	Automated Coagulation Analyzer
Classification Name:	System, Multipurpose for In Vitro Coagulation Studies
Regulatory Class:	Class II
Panel:	Hematology
Product Code:	JPA
Regulation Number	21 CFR 864.5424

Intended Use:
The STA Satellite Max® is a fully automatic clinical analyzer intended to be used by professional laboratory personnel for qualitative and/or quantitative in vitro determination and to perform clotting, chromogenic and immunoassay tests on human venous plasmas (3.2% citrate) the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

3. Predicate Device

Device Name:	STA Satellite® (K082248)
Common Name:	Automated Coagulation Analyzer
Classification Name:	System, Multipurpose for In Vitro Coagulation Studies
Regulatory Class:	Class II
Panel:	Hematology
Product Code:	JPA
Regulation Number	21 CFR 864.5424

4. Device Description / Test Principle

4.1.1. STA Satellite Max® Test Principle

The technological characteristics for the STA Satellite Max® are based on two measurement principles, chronometric (clotting time) and photometry, which includes chromogenic and immunoturbidimetric measurements.

- Chronometry Measurement Principle

The principle consists in measuring changes in the oscillation amplitude of the ball inside the cuvette, using electromagnetic sensors. A reduction in amplitude corresponds to an increase in the medium's viscosity, in other words, clotting.
At constant viscosity, constant pendular swings of the ball are obtained due to the two curved rail tracks at the bottom of the cuvettes and the electromagnetic field created alternately on each side of the measurement cell to maintain this swinging movement. The field frequency is close to the ball's natural oscillation frequency, ensuring very high system sensitivity.
For each measurement cell:

- the magnetic field is created by two drive coils and is adjusted according to the medium's viscosity and the type of test (weak clot for Fibrinogen, normal clot for all the others).
- local infrared (IR) lighting allows light to penetrate the medium and minimizes the interference of outside light.
- the motion of the balls is captured by a camera.

- Photometry Measurement Principle

The detection principle for chromogenic tests on STA Satellite Max® is based on the absorbance (optical density, OD) of monochromatic (405 nm for chromogenic assays or 540 nm for immunologic assays) light passing through a cuvette as an enzymatic or immunological reaction takes place.

4.1.2. STA Satellite Max® Device Description

The STA Satellite Max® is a fully automatic clinical laboratory analyzer intended to perform tests on human plasmas designed as a new version of Stago's previously cleared STA Satellite® (K082248). The given results aid in the diagnosis of Homeostatic disorders and the monitoring of anticoagulant treatment.

At Stago,

- The STA Satellite Max® is the successor to the STA Satellite®;

- The Max generation which also includes: STA R Max® and STA Compact Max ®;

- The STA line which also includes all Stago "STA" analyzers.

The STA Satellite Max has the same intended use as the STA Satellite® (K082248).

Samples and test reagents are loaded into the instrument where sample handling, reagent delivery, analysis and reporting of results are performed automatically. A central processing unit controls

the instrument such as, management of patient results, quality control, system supervision, and support for instrument maintenance and workload optimization.

The analyzer uses Diagnostica Stago reagents in addition to open adaptation of other available reagents. The instrument performs multiple test methodologies in random access, as selected by the user. These include clotting time or clot-based tests (i.e. chronometric measures) and photometric assays on plasma samples.

4.1.3. Reagent Applications in this 510(k) Notification

Six assays were used to demonstrate substantial equivalence, i.e. STA® - Neoplastine CI Plus, STA® - PTTA, STA® - Fibrinogen, STA®-Liquid Anti-Xa UFH, STA®-Liquid Anti-Xa LMWH and STA® - Liatest DDi. These assays cover all the measuring principles, i.e. chronometric, chromogenic and immuno-turbidimetric, and the different reaction set-ups regarding sample dilution (undiluted or diluted). The table below describes the configuration used for each assay.

Table1: Description of the test configuration for the assays used for validation

Assay	Measuring Principle	Sample Dilution Set-Up	Prior regulatory clearance (K#)
STA® - Neoplastine CI Plus	Chronometric	Undiluted	K922040
STA® - PTTA	Chronometric	Undiluted	K792048
STA® - Fibrinogen	Chronometric	Diluted	K840211
STA®-Liquid Anti-Xa UFH	Chromogenic	Diluted	K111822
STA®-Liquid Anti-Xa LMWH	Chromogenic	Diluted	
STA® - Liatest DDi	Immuno-turbidimetric	Undiluted	K162227

The Intended Use Environment is a clinical central/hospital laboratory.

5. Substantial Equivalence

Table 2: STA Satellite Max Similarities Between Candidate and Predicate Devices

Attributes or Characteristics	Predicate Device STA Satellite (K082248)	Candidate Device STA Satellite Max	Justification
Regulatory Classification	JPA, Class II System, Multipurpose for in vitro coagulation studies	Same	Both devices classified under same regulation and product code.
Indications for use	The STA Satellite® Automated Multi-Parametric Analyzer is a fully automatic clinical instrument indicated and intended for the performance of tests on human plasmas , the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.	The STA Satellite Max® is a fully automatic clinical analyzer designed to be used by professional laboratory personnel and to perform tests on human venous plasmas (3.2% citrate) the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy	Same intended use and indication
Anatomical Sites	In vitro testing of human plasma	Same	Both operate on human plasma samples only.
Sample Matrix	Human plasma 3.2% sodium citrate	Same	Same sample matrix and anticoagulant concentration used for testing.
Where Used: hospital, home, ambulance, etc.	Hospital Laboratory or other Health Care Laboratory.	Same	Identical intended use environment.

Attributes or Characteristics	Predicate Device STA Satellite (K082248)	Candidate Device STA Satellite Max	Justification
Measurement Principle	Chronometric method (clotting time): Photo-optical measurement of the oscillation of the metal ball placed in the cuvette Photometric method: light absorption technique provided by a filtered light source (405nm, 540nm).	Same	Identical analytical methodologies.
Control of Fluidic System	PDR (Pipettor Double Resolution) and 3-way electrovalve with a needle kit.	Same	Same fluidic architecture and components.
Needles	One needle for both samples and reagents	Same	Identical operational design.
Operating Environment Temperature	59° - 89.5°F	Same	Same environmental performance range.
User/Patient Data Input	Keyboard, and/or barcode scanner	Same	Identical data entry and sample tracking options.
Specimen Processing	Automatic pipetting and dilution	Same	Same automation and reagent handling principles.

Attributes or Characteristics	Predicate Device STA Satellite (K082248)	Candidate Device STA Satellite Max	Justification
Random Access	Yes	Same	Both support continuous random access operation.
Liquid Level Sensing	Yes	Same	Identical safety and automation feature.
Stat Testing	Yes	Same	Same emergency sample prioritization capability.
Core Analyzer Modules	Coagulation detection cuvettes, optical sensors, reagent cooling units	Same	No changes in mechanical or analytical subsystems.
Measurement Outputs	Clotting time (chronometric) and absorbance (photometric)	Same	Measurement algorithms unchanged.
Products vials stocked	Carousel with 16 positions of different sizes: - 4 positions for 10/15/20 ml vials (diam. 30 mm) - 12 positions for 4/6 ml vials (diam. 23 mm) Within these positions 2 positions can be stirring positions	Carousel with 16 positions of different sizes: - 4 positions for 10/15/20 ml vials (diam. 30 mm) - 12 positions for 4/6 ml vials (diam. 23 mm) Within these positions 4 pre-defined positions can be stirring positions	Both devices use an identical 16 positions reagent carousel with the same vial size compatibility (30 mm and 23 mm diameters). Reagent vials of 4 mL, 5 mL and 6 mL are accommodated within the existing 4/6 mL positions supported by the predicate device; therefore, the reagent container configuration and storage conditions

Attributes or Characteristics	Predicate Device STA Satellite (K082248)	Candidate Device STA Satellite Max	Justification
	Use of adapters (provided with the analyzer) for 18 mm diameter vials	- 2 within diam. 30 mm positions - 2 within diam. 23 mm positions Use of adapters (supplied with the analyzer) for 18 mm diameter vials	remain substantially equivalent with no impact on reagent stability.

Table 3: Differences Between Candidate and Predicate Devices

Attributes or Characteristics	Predicate Device STA Satellite (K082248)	Candidate Device STA Satellite Max	Justification
Data Storage Capacity	2 GB	464 GB	Increased capacity supports larger data retention. No impact on analytical algorithms or results.
Operating System	Windows DOS	Windows 10 Windows 10 IoT Enterprise 2021 LTSC	OS upgrade enhances cybersecurity, stability, and compatibility. Analytical engine and user workflow unchanged.

Attributes or Characteristics	Predicate Device STA Satellite (K082248)	Candidate Device STA Satellite Max	Justification
Connections	Port parallel, floppy disk	USB and RJ45 Enhanced USB, RS232 (native) and dual RJ45	Updated ports.
Dimensions	Height: 784 mm Width: 535 mm Depth: 645 mm	Height: 483 mm Width: 530 mm Depth: 650 mm	Reduced height improves ergonomics; no change to analytical or optical subsystems.
Software Architecture	Single integrated software handling both user interface and analyzer control	Dual software: • GUI (user interface) • ESP (Electronic Software Platform) for analyzer control	Software modularization improves maintainability and cybersecurity. Analytical and timing algorithms unchanged;
Parameters	PT, APTT, Fibrinogen, Anti-Xa (UFH, LMWH), D-Dimers, Antithrombin Activity.	PT, PTT, Fibrinogen, D-Dimer, Anti-Xa.	Same. No new assays introduced.
Industrial PC Platform and Software	Legacy PC with Windows DOS, limited storage and connectivity	Dell Optiplex 3050 PC (Intel Pentium G4400T, 4 GB DDR3, 500 GB HDD, fan-cooled, Windows 10). Kontron K3921 industrial PC (Intel® N97, 8 GB DDR5, dual 256 GB NVMe SSDs, fanless	Hardware modernization addresses obsolescence, enhances cybersecurity, and improves reliability. No change to analytical algorithms, data processing, or test results. Verified

Attributes or Characteristics	Predicate Device STA Satellite (K082248)	Candidate Device STA Satellite Max	Justification
		cooling, Windows 10 IoT Enterprise 2021 LTSC, Trend Micro Safe Lock v3.1.1067, 6 USB, RS232, dual RJ45).	via full system and risk analysis (QUAL_4009). No new risks introduced.

The STA Satellite Max® analyzer and its predicate device, the STA Satellite® (K082248), share the same intended use, core technological characteristics, and principles of operation, supporting a determination of substantial equivalence in clinical performance and functionality.

Standards/Guidance Documents Referenced:

• CLSI EP05-A3 (3rd Edition): Evaluation of Precision of Quantitative Measurement Procedures.
• CLSI EP06-Ed2 (2nd Edition): Evaluation of Linearity.
• CLSI EP09c (3rd Edition): Method Comparison and Bias Estimation Using Patient Samples.
• CLSI EP17-A2 (2nd Edition): Protocols for Determination of Limits of Detection and Limits of Quantitation.
• CLSI H47-A2 and H48 (2nd Edition): One Stage Prothrombin Time (PT) Test for Coagulation Factor Assays.

Performance Characteristics

Performance Characteristics: STA Satellite Max®
Precision
Precision studies were performed in accordance with CLSI EP05-A3 (3rd Edition) using STA Satellite Max reagents. Single site precision was evaluated over 20 days at one external site. Five samples per assay were tested across the analytical measuring range, with two runs per day and two replicates per run. Each run was separated by a minimum of two hours. All assays met predefined acceptance criteria. Summary results (all instruments combined) are provided below.

Assay	Mean Range	Repeatability (%CV)	Between-Run (%CV)	Between-Day (%CV)	Total (%CV)
PT (Neoplastine CI Plus)	12.9–54.0 sec	0.8–1.2	0.3–2.3	0.0–0.5	⩽2.6
APTT (PTTA)	31.7–129.5 sec	0.6–1.4	0.7–2.5	0.0–2.2	⩽ 3.2
Fibrinogen	110–1,023 mg/dL	1.3–2.0	0.6–1.6	0.5–1.5	⩽2.7
Anti-Xa (UFH)	0.23–1.00 IU/mL	2.4–4.3	0.0–2.6	2.2–5.2	⩽6.7
Anti-Xa (LMWH)	0.50–1.77 anti-Xa IU/mL	2.7–3.3	0.0–1.7	1.7–3.8	⩽ 6.4
D-Dimer (Liatest D-DI)	0.27–15.84 µg/mL FEU	1.3–5.1	0.7–2.0	0.4–3.1	⩽6.9

Reproducibility

Multi-site reproducibility testing was conducted in accordance with CLSI EP05-A3 (3rd Edition) over 5 days at three external sites.
Testing was performed by different operators on independent STA Satellite Max® systems using two samples per parameter, each run twice daily with three replicates per run.
Each run was at least two hours apart. The data met all acceptance criteria for between run, between day, between site, and total reproducibility. Multi-Site Reproducibility Summary results (all 3 sites combined) for all assays are provided below.

Multi-Site Reproducibility Results (All 3 Sites Combined):

Assay	Site	N	Sample	Mean	Repeatability (%CV)	Between-Run (%CV)	Between-Day (%CV)	Between-Site (%CV)	Total Precision CV (%)
PT (sec)	All 3 sites combined	90	CCN+	14.3	0.8	0.6	0.0	0.2	**1.0**
		90	CCABN+	33.5	0.7	0.7	0.2	0.8	**1.3**
APTT (sec)	All 3 sites combined	90	CCN+	32.7	0.6	1.5	0.4	1.5	**2.3**
		90	CCABN+	61.6	0.7	1.0	0.0	0.9	**1.5**
FIB (mg/dL)	All 3 sites combined	90	CCN+	317	2.1	3.0	0.0	1.3	**3.9**
		90	CCABN+	157	1.9	1.2	0.2	0.5	**2.4**
UFH (IU/mL)	All 3 sites combined	90	QUAL UFH2	0.23	4.3	4.8	0.0	7.8	**9.6**
		90	QUAL UFH7	0.68	2.5	2.4	1.5	3.8	**5.3**
LMWH	All 3 sites	90	QUAL L8	0.62	6.8	2.3	0.0	5.2	**8.7**

(a-Xa)	combined	90	QUAL L14	1.27	2.7	0.9	1.9	0.0	**3.5**
DDI (µg/mL)	All 3 sites combined	90	LCN	0.27	0.0	0.0	0.0	0.0	**0.0**
		90	LCP	2.30	1.3	0.8	0.7	0.0	**1.7**

All precision and reproducibility results demonstrate that STA Satellite Max® delivers consistent performance across sites and reagent lots.

Detection Limit (LoB/LoD) Study of STA Satellite Max®

A Limit of Blank (LoB) and Limit of Detection (LoD) study was conducted to characterize the analytical sensitivity of the Anti-Xa (UFH and LMWH) and D-Dimer assays on the STA Satellite Max® analyzer in accordance with the CLSI EP17-A2 guideline. The studies were performed using one lot each of STA–Liquid Anti-Xa and STA–Liatest D-DI reagents across two analyzers. The LoB evaluation included 60 blank measurements collected over three days, while the LoD study assessed five low-level samples tested in quadruplicate over the same period. The LoB was determined using the non-parametric 95th percentile, and the LoD was calculated as LoB plus the pooled standard deviation, with homogeneity of variance confirmed by Cochran's test. Final reported values reflect the maximum results observed across analyzers, with LoD values meeting expected performance criteria of 0.10 IU/mL for Anti-Xa and 0.27 µg/mL for D-Dimer.

Limit of Blank (LoB) – STA Satellite Max®

Assay	**Analyzer #18**	**Analyzer #19**	**Reported LoB**	**Unit**
STA-Liquid Anti-Xa (UFH)	0.04	0.03	0.04	IU/mL
STA-Liquid Anti-Xa (LMWH)	0.04	0.04	0.04	anti-Xa IU/mL
STA-Liatest D-DI	0.10	0.09	0.10	µg/mL FEU

Limit of Detection (LoD) – STA Satellite Max®

Assay	**Analyzer #18**	**Analyzer #19**	**Reported LoD**	**Unit**
STA-Liquid Anti-Xa (UFH)	0.08	0.09	0.09	IU/mL
STA-Liquid Anti-Xa (LMWH)	0.09	0.09	0.09	anti-Xa IU/mL
STA-Liatest D-DI	0.17	0.20	0.20	µg/mL FEU

All determined LoB and LoD values meet the performance acceptance criteria outlined in CLSI EP17-A2, confirming robust low-end analytical sensitivity for both the Anti-Xa (UFH and LMWH) and D-Dimer assays.

Limit of Quantification (LoQ) Study of STA Satellite Max®
A Limit of Quantification (LoQ) study was performed to determine the lowest concentration at which the STA Satellite Max® analyzer can reliably quantify Fibrinogen, D-Dimer, and Anti-Xa (UFH and LMWH) assays with acceptable accuracy and precision. The study followed CLSI EP17-A2 guidelines. Low-level pooled plasma samples were tested across two analyzers, multiple reagent and calibrator lots, and over three days to ensure robust evaluation. LoQ was determined using total error, defined as the sum of bias and imprecision, and compared against predefined allowable limits. The LoQ for each assay was established as the lowest concentration meeting acceptance criteria across analyzers, with final values reflecting a worst-case approach across reagent lots. The established Limit of Quantification (LoQ) for STA Satellite Max® were as follows: • STA–Fibrinogen: 66 mg/dL • STA–Liquid Anti-Xa (LMWH): 0.15 anti-Xa IU/mL • STA–Liquid Anti-Xa (UFH): 0.15 IU/mL • STA–Liatest D-DI: 0.34 µg/mL FEU
Linearity Study of Satellite Max®
A linearity study was conducted to confirm that the STA Satellite Max® analyzer provides accurate, proportional results across the claimed analytical measurement ranges for the Fibrinogen, Anti-Xa (UFH and LMWH), and D-Dimer assays. The study was performed in accordance with CLSI EP06-A and CLSI EP06 (2nd Edition), using one reagent lot on two analyzers. Each assay was evaluated across its defined measuring range using 11 serial dilution levels tested in quadruplicate. Linearity was assessed through regression analysis to evaluate proportionality, deviation from linearity, and bias against predefined acceptance criteria. The results confirmed that all assays demonstrated acceptable linearity, with measured concentrations directly proportional to analyte levels across the claimed ranges. The established linear ranges were as follows: • STA–Fibrinogen: 60 to 1200 mg/dL • STA–Liquid Anti-Xa (LMWH): 0.10 to 2.00 anti-Xa IU/mL • STA–Liquid Anti-Xa (UFH): 0.10 to 1.10 IU/mL • STA–Liatest D-DI: 0.27 to 20.00 µg/mL FEU
Method Comparison
Method comparison studies were performed according to CLSI EP09c guidelines at three external sites. Samples spanning the entire measuring range were tested on both the predicate device (STA Satellite®) and subject device (STA Satellite Max®). Method comparison results are presented in the table below and include slope and intercept values (including outliers), the number of samples tested (n), and correlation coefficients. Statistical analysis was performed using Passing–Bablok regression or Deming regression, as appropriate based on data distribution. A summary of regression results pooled across all sites is provided below.

Assay	n (Total Samples)	Slope (95% CI)	Intercept (95% CI)	$r_{Spearman}$ (95% CI)
PT (Neoplastine CI Plus)	180	1.02 (1.01–1.03)	−0.27 (−0.45 to −0.10)	0.998 (0.997 to 0.998)
APTT (PTTA)	204	1.00 (0.99–1.01)	−0.40 (−0.53 to 0.01)	0.999 (0.998 to 0.999)
Fibrinogen	198	0.98 (0.97–1.00)	−3.50 (−10.92 to 2.45)	0.989 (0.986 to 0.992)
Anti-Xa (UFH)	192	1.00 (1.00–1.00)	0.00 (0.00 to 0.01)	0.991 (0.988 to 0.994)
Anti-Xa (LMWH)	155	0.99 (0.98–1.00)	0.02 (0.01 to 0.03)	0.996 (0.994 to 0.997)
D-Dimer (Liatest D-DI)	178	1.01 (1.00–1.03)	−0.01 (−0.03 to 0.02)	0.998 (0.997 to 0.998)

Factor Sensitivity Study of STA Satellite Max®

Factor sensitivity studies were conducted to assess the responsiveness of the STA-Neoplastine CI Plus reagent to key extrinsic coagulation factors (FII, FV, FVII, and FX) on the STA Satellite Max® analyzer. The studies were performed in accordance with CLSI guidelines using one reagent lot across two analyzers. Single-factor deficient plasmas were mixed with normal pooled plasma to create a range of factor concentrations, and PT was measured to determine the factor level at which results exceeded the established normal range. All factors met the predefined acceptance criterion of at least 30% activity, demonstrating consistent and reproducible factor sensitivity across both analyzers.

Conclusion

Based on the substantial equivalence comparison and the results of the analytical performance evaluations, the STA Satellite Max® analyzer was shown to be substantially equivalent to the cleared and currently marketed predicate device, STA Satellite® (K082248).

The differences between the subject and predicate devices do not affect the safety or effectiveness of the system. The STA Satellite Max® provides equivalent analytical performance and maintains the same intended use, operating principles, and clinical utility as the predicate device.

Assay Cut-off - Not applicable

Clinical Studies

Clinical Sensitivity - Not applicable

Clinical Specificity - Not applicable

Clinical Cut-off - Not applicable

Reference Interval - Not applicable