510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K253658

B Applicant

Diagnostica Stago, Inc.

C Proprietary and Established Names

STA Satellite Max

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JPA	Class II	21 CFR 864.5424 – Multipurpose System For In Vitro Coagulation Studies	HE – Hematology

II Submission/Device Overview:

A Purpose for Submission:

New device

B Type of Test:

Quantitative, clotting time and enzymatic activity or quantification of factors related to coagulation.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for 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.

C Special Conditions for Use Statement(s):
Rx – For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

The STA Satellite Max is a fully automated 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.

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

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.

B Instrument Description Information:

1. Instrument Name:

   STA Satellite Max

2. Specimen Identification:

   Barcode reader or manual entry of specimen identification (ID).

3. Specimen Sampling and Handling:

   There are two types of sample loading. The sample carousel can be totally or partially loaded outside the analyzer and placed back into the analyzer. Single loading of the tubes directly into the analyzer via the opening in the sample carousel cover is also possible. Following centrifugation of the collection tubes, the user loads these tubes, without their caps, into the carousel with the barcode label positioned in front of the opening in the carousel. The analyzer automatically detects the tubes loaded into the carousel and their position by the Positive Identification system. For sampling, the rotor rotates to present the tube at the sampling position. The needle then draws the sample volume required for the test to be performed. The tube can be brought to the sampling position several times.

4. Calibration:

   The STA Satellite Max automatically requires calibration for each lot of reagent used. Calibration can be automated by using calibration curves provided with the reagent or performed manually with titrated calibrators depending on the assay. No assays can be run without valid calibration.

5. Quality Control:

   Quality controls are defined by the methodology for each test and each methodology defines the number of levels and frequency of QC. For each methodology, it is mandatory to run at least one QC level per day. The system can automatically run QC and flag when control values are outside of pre-determined ranges. Patient sampling starts when all conditions are met, including QC and calibrations within range.

V Substantial Equivalence Information:

A Predicate Device Name(s):
STA Satellite

B Predicate 510(k) Number(s):
K082248

C Comparison with Predicate(s):

Device & Predicate Device(s):	K253658	K082248
Device Trade Name	STA Satellite Max	STA Satellite
General Device Characteristic Similarities		
Intended Use/Indications For Use	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.	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.

Sample Matrix	Human plasma, 3.2% sodium citrate	Same
Regulatory Classification	JPA, Class II System, Multipurpose for in vitro coagulation studies	Same
Measurement Principle	Chronometric method (clotting time): measurement of the oscillation of the metal ball placed in the cuvette Photometric method: light absorption technique provided by a filtered light source (405 nm, 540 nm)	Same
Testing environment	Clinical laboratory	Same
Control of Fluidic System	PDR (Pipettor Double Resolution) and 3-way electrovalve with a needle kit	Same
Needles	One needle for both samples and reagents	Same
Operating Environment Temperature	59-89.5 F	Same
User/Patient Data Input	Keyboard and/or barcode scanner	Same
Specimen Processing	Automatic pipetting and dilution	Same
Random access	Yes	Same
Liquid Level Sensing	Yes	Same
Stat Testing	Yes	Same
Core Analyzer Modules	Coagulation detection cuvettes, optical sensors, reagent cooling units	Same
Measurement Outputs	Clotting time (chronometric) and absorbance (photometric)	Same
General Device Characteristic Differences	**K253658**	**K082248**
Product vials stocked	Carousel with 16	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. • 2 within diam. 30 mm positions • 2 within diam. 23 mm positions Use of adapters (provided with the analyzer) for 18 mm diameter vials	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. Use of adapters (provided with the analyzer) for 18 mm diameter vials
Data Storage Capacity	464 GB	2 GB
Operating System	Windows 10 (current) Windows 10 IoT Enterprise 2021 LTSC	Windows DOS
Connections	USB and RJ45 (current) Enhanced USB, RS232 (native) and dual RJ45	Port parallel, floppy disk
Dimensions	Height: 483 mm Width: 530 mm Depth: 650 mm	Height: 784 mm Width: 535 mm Depth: 645 mm
Software Architecture	Dual software: • GUI (user interface) • ESP (Electronic Software Platform) for analyzer control	Single integrated software handling both user interface and analyzer control.
Parameters	PT, APTT, Fibrinogen, D-Dimer, Anti-Xa (UFH, LMWH)	PT, APTT, Fibrinogen, Anti-Xa (UFH, LMWH), D-Dimers, Antithrombin Activity
Industrial PC Platform and Software	Dell Optiplex 3050 PC (Intel Pentium G4400T, 4 GB DDR3, 500 GB HDD, fan-cooled, Windows 10)	Legacy PC with Windows DOS, limited storage and connectivity

VI Standards/Guidance Documents Referenced:

CLSI EP06: Evaluation of Linearity of Quantitative Measurement Procedures – 2nd Edition
CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – 3rd Edition
CLSI EP09c: Method Comparison and Bias Estimation Using Patient Samples – 3rd Edition
CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – 2nd Edition
CLSI H47-A2: One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin time (APTT) Test, Approved Guideline – 2nd Edition
CLSI H21-A5: Collection Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays
IEC 62304 Edition 1.1 2015-06 Consolidated Version Medical Device Software – Software life cycle processes
IEC 61326-2-6 Edition 4.0 2025-06 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: IVD medical equipment
IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability
A single site repeatability study was performed in accordance with *CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – 3rd Edition.* Six assays were evaluated: PT (K922040), APTT (K792048), FIB (fibrinogen, K840211), Anti-Xa (UFH (unfractionated heparin), K111822), Anti-Xa (LMWH (low molecular weight heparin), K111822) and D-Dimer (K162227). The study was conducted using five samples per parameter, three patient samples and two quality control samples, covering the measurement range, with one lot of each reagent. The five samples were assayed over 20 days. Two runs were performed per day with two replicates per sample per run. The runs were randomly distributed between two operators. Each assay was performed on three instruments. For each assay, standard deviation (SD) and coefficient of variation (CV) were calculated to determine the following precision parameters: within-run, between-run, between-day, between-instrument and within-site. The results of the studies met the predefined acceptance criteria.

PT (STA-Neoplastine CI Plus (sec))

Sample	N	Mean	Within-Run		Between-Run		Between-Day		Between-Instrument		Within-Site	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	240	12.9	0.133	1.0	0.043	0.3	0.067	0.5	0.000	0.0	0.155	1.2
2	240	38.7	0.428	1.1	0.675	1.7	0.000	0.0	0.199	0.5	0.824	2.1
3	240	54.0	0.450	0.8	1.250	2.3	0.000	0.0	0.502	0.9	1.420	2.6
4	240	14.0	0.122	0.9	0.090	0.6	0.000	0.0	0.074	0.5	0.169	1.2
5	240	24.4	0.301	1.2	0.314	1.3	0.055	0.2	0.294	1.2	0.528	2.2

APTT (STA-PTTA (sec))

Sample	N	Mean	Within-Run		Between-Run		Between-Day		Between-Instrument		Within-Site	
			SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)
1	240	31.7	0.18	0.6	0.232	0.7	0.192	0.6	0.000	0.0	0.351	1.1
2	240	102.8	0.704	0.7	2.297	2.2	2.240	2.2	0.000	0.0	3.285	3.2
3	240	129.5	1.405	1.1	3.177	2.5	0.000	0.0	0.752	0.6	3.554	2.7
4	240	35.5	0.228	0.6	0.495	1.4	0.156	0.4	0.000	0.0	0.567	1.6
5	240	59.9	0.856	1.4	0.838	1.4	1.025	1.7	0.000	0.0	1.577	2.6

FIB (STA-Fibrinogen (mg/dL))

Sample	N	Mean	Within-Run		Between-Run		Between-Day		Between-Instrument		Within-Site	
			SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)
1	240	548	9.311	1.7	5.635	1.0	4.563	0.8	1.553	0.3	11.903	2.2
2	240	767	10.478	1.4	6.745	0.9	5.438	0.7	3.576	0.5	14.059	1.8
3	240	1023	13.367	1.3	15.916	1.6	15.144	1.5	6.076	0.6	26.424	2.6
4	240	277	5.530	2.0	4.306	1.6	2.405	0.9	1.108	0.4	7.492	2.7
5	240	110	1.712	1.6	0.662	0.6	0.538	0.5	0.304	0.3	1.937	1.8

UFH – STA Liquid Anti-Xa (IU/mL)

Sample	N	Mean	Within-Run		Between-Run		Between-Day		Between-Instrument		Within-Site	
			SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)
1	240	0.23	0.010	4.3	0.000	0.0	0.008	3.5	0.001	0.4	0.013	5.7
2	240	0.51	0.014	2.7	0.006	1.2	0.013	2.5	0.010	2.0	0.022	4.3
3	240	1.00	0.024	2.4	0.005	0.5	0.022	2.2	0.034	3.4	0.048	4.8
4	240	0.27	0.009	3.3	0.007	2.6	0.014	5.2	0.000	0.0	0.018	6.7
5	240	0.70	0.017	2.4	0.013	1.9	0.024	3.4	0.020	2.9	0.038	5.4

LMWH – STA Liquid Anti-Xa (IU/mL)

Sample	N	Mean	Within-Run		Between-Run		Between-Day		Between-Instrument		Within-Site	
			SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)
1	240	0.50	0.016	3.2	0.000	0.0	0.019	3.8	0.020	4.0	0.032	6.4
2	240	1.40	0.038	2.7	0.022	1.6	0.027	1.9	0.035	2.5	0.062	4.4
3	240	1.77	0.053	3.0	0.030	1.7	0.030	1.7	0.041	2.3	0.079	4.5
4	240	0.86	0.026	3.0	0.014	1.6	0.018	2.1	0.022	2.6	0.041	4.8
5	240	1.58	0.052	3.3	0.000	0.0	0.030	1.9	0.055	3.5	0.081	5.1

D-Dimer (STA-Liatest D-DI (µg/mL))

Sample	N	Mean	Within-Run		Between-Run		Between-Day		Between-Instrument		Within-Site	
			SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)
1	240	0.75	0.038	5.1	0.013	1.7	0.023	3.1	0.022	2.9	0.052	6.9
2	240	8.43	0.215	2.6	0.057	0.7	0.052	0.6	0.372	4.4	0.436	5.2
3	240	15.84	0.371	2.3	0.198	1.3	0.349	2.2	0.881	5.6	1.037	6.5
4	240	0.27	0.008	3.0	0.002	0.7	0.001	0.4	0.000	0.0	0.008	3.0
5	240	2.30	0.030	1.3	0.047	2.0	0.040	1.7	0.045	2.0	0.082	3.6

Reproducibility

The multi-site reproducibility study was conducted in accordance with *CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – 3rd Edition.* Six assays were evaluated: PT, APTT, FIB (fibrinogen), Anti-Xa (UFH), Anti-Xa (LMWH) and D-Dimer. The study was conducted at three US sites (one analyzer per site) using two levels quality control samples over five days with two runs per day and three replicates per sample using two operators. For each assay, SD and CV were calculated to determine the following precision parameters, for each assay and for all sites combined: within-run, between-run, between-day, between-site and total precision. The results of the studies met the predefined acceptance criteria.

Multi-site precision: STA Satellite Max (all sites combined)

Assay	Sample	N	Mean	Within-Run		Between-Run		Between-Day		Between-Site		Total Precision	
				SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)
PT (sec)	CCN+	90	14.3	0.109	0.8	0.081	0.6	0.000	0.0	0.022	0.2	0.137	1.0
	CCABN+	90	33.5	0.239	0.7	0.245	0.7	0.057	0.2	0.259	0.8	0.433	1.3
APTT (sec)	CCN+	90	32.7	0.211	0.6	0.485	1.5	0.129	0.4	0.498	1.5	0.738	2.3
	CCABN+	90	61.6	0.458	0.7	0.611	1.0	0.000	0.0	0.550	0.9	0.941	1.5
FIB (mg/dL)	CCN+	90	317	6.723	2.1	9.543	3.0	0.000	0.0	4.165	1.3	12.394	3.9
	CCABN+	90	157	3.017	1.9	1.961	1.2	0.272	0.2	0.780	0.5	3.692	2.4
UFH (anti-Xa IU/mL)	QUAL UFH2	90	0.23	0.010	4.3	0.011	4.8	0.000	0.0	0.018	7.8	0.022	9.6
	QUAL UFH7	90	0.68	0.017	2.5	0.016	2.4	0.010	1.5	0.026	3.8	0.036	5.3
LMWH (anti-Xa IU/mL)	QUAL LMWH8	90	0.62	0.042	6.8	0.014	2.3	0.000	0.0	0.032	5.2	0.054	8.7
	QUAL LMWH14	90	1.27	0.034	2.7	0.012	0.9	0.024	1.9	0.000	0.0	0.044	3.5
D-Dimer (µg/mL)	LCN (normal)	90	0.27	0.000	0.0	0.000	0.0	0.000	0.0	0.000	0.0	0.000	0.0
	LCP (abnormal)	90	2.30	0.031	1.3	0.019	0.8	0.016	0.7	0.000	0.0	0.40	1.7

2. Linearity:

A linearity study was conducted in accordance with *CLSI EP06: Evaluation of Linearity of Quantitative Measurement Procedures – 2nd Edition* to verify the linear response over the expected measuring range for fibrinogen, Anti-Xa (UFH, LMWH) and D-Dimer assays on

the STA Satellite Max. The linearity study was performed with one reagent lot and two instruments. Frozen patient plasmas with high and low analyte concentrations near the upper and lower limits of the expected measuring range were used to create 11 dilutions per assay spanning the targeted ranges, with four replicates per dilution. The linear ranges were verified such that all acceptance criteria were met.

Analyte/Assay	Linear Range
STA-Fibrinogen (mg/dL)	66 to 1200
STA-Liquid Anti Xa LMWH (IU/mL)	0.15 to 2.00
STA-Liquid Anti Xa UFH (IU/mL)	0.15 to 1.10
STA-Liatest D-DI (µg/mL)	0.34 to 20.00

3. Analytical Specificity/Interference:

Not Applicable

4. Detection Limit and Assay Reportable Range:

The Limit of Blank (LoB) was determined by measuring five deficient patient plasmas with known Anti-Xa level ≤ 0.05 IU/mL for the Anti-Xa assay, tested in four replicates over three days in a single run per day. For the D-Dimer assay, five different lots of STA Owren Koller buffer (diluent) were used. The LoB was calculated as the 95th percentile using the non-parametric method for each lot as the dataset showed non-normal distribution. The claimed LoB was the highest 95th percentile value across the two analyzers.

The Limit of Detection (LoD) was determined by measuring five low patient plasmas with known analyte level ranging from one to five times the estimated LoB value. The samples were assayed over three days with one run per day with four replicates over three days. LoD was calculated as the LoB + 1.653 x SD of the replicates for the samples and the highest LoD across the two analyzers was the LoD claim.

The Limit of Quantitation (LoQ) was determined by measuring five low level plasma samples tested in replicates of four over three days in a single run per day. The study utilized two analyzers and two reagent lots. The final LoQ for each parameter was determined using total error, defined as the sum of bias and imprecision, and compared against predefined allowable limits. For each reagent lot, the LoQ was defined as the lowest concentration of measurand for which all instruments met the acceptance criteria, and the final LoQ for each parameter was defined and the highest LoQ obtained across all reagent lots.

Analyte/Assay	LoB	LoD	LoQ
STA-Liatest D-DI (µg/mL)	0.10	0.20	0.34
STA-Liquid anti Xa LMWH (IU/mL)	0.04	0.09	0.15
STA-Liquid anti Xa UFH (IU/mL)	0.04	0.09	0.15
STA-Fibrinogen (mg/dL)	Not applicable	Not applicable	0.66

A factor sensitivity study was conducted for PT to assess instrument performance. The study was performed for coagulation factors II, V, VII and X using one lot of STA-Neoplastine CI

Plus reagent on two analyzers. For each of the extrinsic factors, normal pooled plasma was mixed with each of the single factor-deficient patient plasmas to produce eight individual dilutions measured in duplicate. The factor sensitivity was defined as the factor level at which the PT test result rises above the upper limit of the established normal range. The study verifies factor sensitivity for the PT assay at the levels shown in the table below:

Extrinsic Factor	Mean (%)
Factor II	49%
Factor V	48%
Factor VII	49%
Factor X	47%

B Comparison Studies:

1. Method Comparison with Predicate Device:

The method comparison study was performed and evaluated the performance of the STA Satellite Max by demonstrating equivalence to the cleared STA Satellite (K082248) at three US sites. Samples were collected in 3.2% trisodium citrate anticoagulant. A total of 1,107 samples were analyzed, fresh patient plasmas and frozen plasma samples (thawed). Six assays were evaluated: STA-Neoplastine CI Plus (PT), STA-PTTA (APTT), STA-Fibrinogen (Fibrinogen), STA-Liquid Anti-Xa (UFH), STA-Liquid Anti-Xa (LMWH) and STA-Liatest D-DI (D-Dimer). The samples covered the measuring range of each assay. The results of the method comparison study met the pre-defined acceptance criteria.

STA Satellite Max: Passing-Bablok Regression

Parameter	N	Sample Range	Intercept (95% CI)	Slope (95% CI)	R Spearman (95% CI)
PT (sec)	180	12.0 – 82.2	-0.27 (-0.45, -0.10)	1.02 (1.01, 1.03)	0.998 (0.997, 0.998)
APTT (sec)	204	23.3 – 151.9	-0.40 (-0.53, -0.01)	1.00 (0.99, 1.01)	0.999 (0.998, 0.999)
Fibrinogen (mg/dL)	198	79 - 1194	-3.50 (-10.92, 2.45)	0.98 (0.97, 1.00)	0.989 (0.986, 0.992)
UFH (IU/mL)	192	0.10 – 1.09	0.00 (0.00, 0.01)	1.00 (1.00, 1.00)	0.991 (0.988, 0.994)
LMWH (IU/mL)	155	0.10 – 2.00	0.02 (0.01, 0.03)	0.99 (0.98, 1.00)	0.996 (0.994, 0.997)
D-Dimer (µg/mL)	178	0.29 – 19.83	-0.01 (-0.03, 0.02)	1.01 (1.00, 1.03)	0.998 (0.997, 0.998)

2. Matrix Comparison:

Not applicable

C Other Supportive Instrument Performance Characteristics Data:

1. Carry-Over

Carry-over studies evaluated potential reagent contamination and the impact of STA-Wash integration when used with STA-Cleaner Solution and STA-Desorb U. The study evaluated the potential for contamination when one lot of a susceptible assay (STA-Liquid Anti-Xa (K111822)) was exposed to one lot each of the following contaminant reagents: STA-Fibrinogen, STA-Neoplastine CI Plus and STA-NeoPTimal. Three lots of STA-Wash were evaluated on six STA Satellite Max analyzers using two samples, STA-Quality HNF/UFH 3 and STA-Quality HBPM/LMWH 8, which are prepared from native human plasma. For each contaminant and each sample, a reference series (contaminable test STA-liquid Anti-Xa heparin assay) and a mixed series (contaminate tests - STA – Fibrinogen 5, STA – Neoplastine CI+, STA – NeoPTimal mixed with contaminable test (STA-Liquid Anti-Xa assay)) were tested. The results were within the predefined acceptance criteria, demonstrating effective decontamination when using STA-Wash with STA-Cleaner Solution and STA-Desorb U.

A second study was performed to confirm that the use of STA-Wash does not affect the performance of the APTT, PT or Anti-Xa assays. The study compared results obtained with the addition of STA-Wash versus without STA-Wash, using one lot of STA-Wash on one STA Satellite Max analyzer. Two levels of QC material were tested for each assay. Two series were tested with 10 replicates in the reference series, followed by 10 replicates of the modified test set up series (needle washing added before the sample and reagent collection). All results were within the predefined acceptance criteria, demonstrating that the use of STA-Wash does not affect the performance of APTT, PT or Anti-Xa assays.

2. Sample Stability Study

A 24-month stability study was performed using 240 fresh whole blood samples collected in 3.2% citrate tubes then aliquoted into one mL plasma samples. The samples were tested within four hours of collection for PT, APPT, Fibrinogen and D-Dimer on the STA R Max Each aliquot was frozen at ≤-70ºC. Ten samples were assayed at timepoints T (months) = 3, 6, 11, 18, 22, and 24 on one analyzer, the STA R Max. Passing-Bablok regression analysis was performed between fresh and frozen samples for all four assays. All four assays met the predefined acceptance criteria confirming that patient plasma stored at ≤-70ºC remain stable for up to 22 months for PT, APTT, Fibrinogen and D-Dimer assays.

A 12-month stability study was conducted to assess the stability of Anti-Xa activity in 3.2% citrate plasma. Thirty fresh whole blood samples were collected and processed in one mL aliquots to allow for sets of 7–9 samples to be combined and tested at each timepoint. The samples were tested within four hours from collection for LMWH and UFH using the STA R Max analyzer. Each tube was stored frozen at ≤-70ºC immediately after testing. Samples were thawed for testing at their specified times: T= 3, 6, 9, and 12 months. At each timepoint, 7–9 frozen samples were tested. Passing-Bablok regression analysis was performed between fresh and frozen samples. Both assays met the predefined acceptance criteria confirming that patient plasma stored at ≤-70ºC remain stable for up to 10 months for LMWH and UFH assays.

3. Fresh-Frozen Plasma Comparability Study

   A fresh-frozen comparability study was performed for citrated plasma samples across six assays: PT, APTT, FIB, UFH, LMWH, and D-DI. A total of more than 50 patient samples per assay were tested, covering the full analytical measuring range. Samples were tested fresh within four hours of collection and then stored at ≤-70ºC for one day to four months. Following storage, samples were thawed at 37ºC and retested within two hours. Testing was conducted using two STA Satellite Max analyzers Passing-Bablok regression analysis was performed and demonstrated results obtained from fresh and frozen plasmas were comparable and met the predefined acceptance criteria, demonstrating that patient plasma frozen at ≤-70ºC are equivalent to fresh samples within one freeze-thaw cycle.

4. Electrical safety and electromagnetic compatibility (EMC) testing were performed, and the system was found to be acceptable.

5. Software and cybersecurity documentation was reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.