



September 24, 2026

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

Re: K260214

Trade/Device Name: STA® - Liquid Anti-Xa
Regulation Number: 21 CFR 864.7525
Regulation Name: Heparin assay
Regulatory Class: Class II
Product Code: KFF
Dated: January 22, 2026
Received: January 23, 2026

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Indications for Use

510(k) Number (if known)

K260214

Device Name

STA® - Liquid Anti-Xa

Indications for Use (Describe)

STA® - Liquid Anti-Xa: The STA® Liquid Anti-Xa kits are intended for use with STA-R® family, STA Compact® and STA Satellite® analyzers, for the quantitative determination of the plasma levels of unfractionated (UFH) and low molecular weight (LMWH) heparins by measuring their anti-Xa activity on antithrombin in a competitive assay using a synthetic chromogenic substrate.

STA® - Multi Hep Calibrator: The STA® -Multi Hep Calibrator is a set of calibrator plasmas intended for use with STA-R®, STA Compact® and STA Satellite® analyzers, for the calibration of heparin (UFH and LMWH) activity assay by measuring the anti-xa activity.

STA® - Quality HNF/UFH: The STA® -Quality HNF/UFH kit is set of two plasmas intended for the quality control of unfractionated heparin (UFH) activity assay by measuring the anti-Xa activity performed on STA-R®, STA Compact®, and STA Satellite® analyzers.

STA® - Quality HBPM/LMWH: STA® - Quality HBPM/LMWH kit is a set of two plasmas intended for the quality control of low molecular weight heparin (LMWH) activity assay by measuring the anti-Xa activity performed on STA-R®, STA Compact®, and STA Satellite® analyzers.

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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**SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

This 510(k) summary of safety and effectiveness is submitted in accordance with the requirements of 21 CFR 807.92.

Date of Preparation: 09/17/2026

1. 510(k) Number

K260214

2. 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

3. Device

Device Trade Name: STA®-Liquid Anti-Xa
Classification Name: Heparin Assay
Regulatory Class: Class II
Panel: Hematology
Product Code: KFF
Regulation Number: 21 CFR 864.7525

4. Intended Use

STA® Liquid Anti-Xa: The STA® Liquid Anti-Xa kits are intended for use with STA-R® family, STA Compact® and STA Satellite® analyzers for the quantitative determination of the plasma levels of unfractionated (UFH) and low molecular weight (LMWH) heparins by measuring their anti-Xa activity on antithrombin in a competitive assay using a synthetic chromogenic substrate.

STA® - Multi Hep Calibrator: The STA® -Multi Hep Calibrator is a set of calibrator plasmas intended for use with STA-R®, STA Compact® and STA Satellite® analyzers, for the calibration of heparin (UFH and LMWH) activity assay by measuring the anti-xa activity.

STA® - Quality HNF/UFH: The STA® -Quality HNF/UFH kit is set of two plasmas intended for the quality control of unfractionated heparin (UFH) activity assay by measuring the anti-Xa activity performed on STA-R®, STA Compact® , and STA Satellite® analyzers.

STA® - Quality HBPM/LMWH: STA® - Quality HBPM/LMWH kit is a set of two plasmas intended for the quality control of low molecular weight heparin (LMWH) activity assay by measuring the anti-Xa activity performed on STA-R®, STA Compact®, and STA Satellite® analyzers.

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510(k) Summary



5. Predicate Device

Device Trade Name: STA® Liquid Anti-Xa
Manufacturer: Diagnostica Stago
Classification Name: Heparin Assay
Regulatory Class: Class II
Panel: Hematology
Product Code: KFF
Regulation Number: 21 CFR 864.7525
510(k) Number: K111822

6. Device Description / Test Principle

6.1.1. STA Liquid Anti-Xa Test Principle

6.1.1.1. Photometric Measurement Principle

The STA® Liquid Anti-Xa assay is a one-step chromogenic assay based on the physiological activity of Factor Xa and its inhibition by the heparin–antithrombin complex.

Under normal conditions, Factor Xa cleaves its natural substrate, prothrombin, generating thrombin, which is responsible for fibrin clot formation. In the presence of heparin, a competitive inhibitory mechanism occurs whereby heparin forms a complex with antithrombin (AT) specific to the patient. This heparin–antithrombin complex inhibits Factor Xa and is responsible for the anticoagulant activity of heparin.

In the assay, a defined amount of bovine Factor Xa is added to a plasma substrate mixture.

Two reactions occur simultaneously:

- Hydrolysis of the chromogenic substrate by Factor Xa
- Inhibition of Factor Xa by the heparin antithrombin complex

After a defined incubation period allowing the competitive reactions to reach equilibrium, residual (uninhibited) Factor Xa cleaves the chromogenic substrate, releasing paranitroaniline (pNA). The amount of pNA released is inversely proportional to the concentration of heparin present in the sample.

The absorbance of pNA is measured photometrically at 405 nm. Anti-Factor Xa activity is determined by comparison to a calibration curve generated from heparin standards.

6.1.1.2. Measurement of Absorbance

Samples and reagents are automatically mixed and incubated on the analyzer. Following incubation, residual Factor Xa cleaves the chromogenic substrate, and the analyzer measures the change in absorbance at 405 nm. Anti-Factor Xa activity is calculated relative to a calibration curve established using heparin reference standards.



6.1.2. STA Liquid Anti-Xa Device Description

The STA® Liquid Anti-Xa assay is an in-vitro diagnostic chromogenic assay used for the quantitative determination of anti-Factor Xa activity corresponding to unfractionated heparin (UFH) and low molecular weight heparin (LMWH) in human plasma.

The assay measures the inhibition of a defined amount of bovine Factor Xa by the antithrombin-heparin complex present in patient plasma. Residual Factor Xa activity is measured using a chromogenic substrate, and results are determined photometrically.

The STA® Liquid Anti-Xa assay is intended for use on STA® line coagulation analyzers, including the STA R Max 3 and has no direct patient contact.

6.1.3. Device Characteristics

STA® Liquid Anti-Xa kits contain ready-to-use liquid reagents:

Table 1: STA®-Liquid Anti-Xa Kit Description

Component	Description
Reagent 1	Chromogenic substrate
Reagent 2	Bovine Factor Xa

The reagents are liquid and require no reconstitution.

Engineering drawings and schematics are not applicable, as the device consists solely of reagents.

Reagent 1 is the chromogenic substrate. When cleaved by residual Factor Xa, it releases a colored product proportional to Factor Xa activity.

Reagent 2 contains bovine Factor Xa. In the presence of patient plasma, heparin bound antithrombin inhibits a portion of Factor Xa. The remaining active Factor Xa cleaves Reagent 1, producing a colorimetric signal that is inversely proportional to heparin concentration.

The reagents are ready-to-use liquid and require no reconstitution.

Engineering drawings, schematics, etc. are not applicable to the device as the devices are reagents and figures are not pertinent to describe the device.



STA® Liquid Anti Xa kits are available in below sizes:

Table 1: STA® Liquid Anti Xa Kit Descriptions

STA® Liquid Anti-Xa 4	STA® Liquid Anti-Xa 8
6 x 4 ml vials of Reagent 1	6 x 8 ml vials of Reagent 1
6 x 4 ml vials of Reagent 2	6 x 8 ml vials of Reagent 2

Assay Principle

The assay measures inhibition of Factor Xa by the antithrombin heparin complex using a chromogenic substrate. The generated color is inversely proportional to heparin concentration.

Associated Quality Controls and Calibrators

The STA® Quality HNF/UFH (K111822) and STA® Quality HBPM/LMWH (K111822) are used to perform quality control for the anti-Xa heparin assay.

The STA® Multi Hep Calibrator (K111822) is used for calibration of the STA® Liquid Anti-Xa assay.

Analyzers

STA® Liquid Anti-Xa kits are intended to be used with the families of analyzers manufactured by Stago (Table 2).

Table 2: Analyzers used with STA® Liquid Anti-Xa

Family	STA® Liquid Anti-Xa 4	STA® Liquid Anti-Xa 8
STA-R® Family	X	X
STA Compact®	X	X
STA Satellite®	X	Not Applicable

The STA-R® family analyzers includes the STA-R® (K983460), STA-R® Evolution (K093001), and STA-R Max 3 (K212183). The STA® Liquid Anti-Xa can also be used on STA Compact® (K093167) and STA Satellite® (K082248) analyzers.

7. Substantial Equivalence

Table 3: STA® Liquid Anti-Xa Candidate and Predicate Devices Substantial Equivalence Table

Attribute / Characteristic	Predicate Device STA® Liquid Anti-Xa (K111822)	Candidate Device STA Liquid Anti-Xa (K260214)	Equivalence Determination / Justification
Device Type	In vitro diagnostic (IVD) reagent	In vitro diagnostic (IVD) reagent	Same.
Intended Use / Indications for Use	Quantitative determination of unfractionated heparin (UFH), low molecular weight heparin (LMWH) in citrated human plasma.	Quantitative determination of unfractionated heparin (UFH), low molecular weight heparin (LMWH) in citrated human plasma.	Same.
Analyte(s) Measured	UFH and LMWH (anti-Xa activity)	UFH and LMWH (anti-Xa activity)	Same.
Assay Method	Chromogenic method (measurement of the chromogenic substrate at 405 nm)	Chromogenic method (measurement of the chromogenic substrate at 405 nm)	Same.
Test Principle	Measurement of anti-Xa activity in terms of antithrombin-heparin complex. The activity of the complex is a function of the level of heparin	Measurement of anti-Xa activity in terms of antithrombin-heparin complex. The activity of the complex is a function of the level of heparin	Same.
Kit Contents	Two liquid reagents: Reagent 1: Chromogenic substrate. Reagent 2: Bovine Factor Xa	Two liquid reagents: Reagent 1: Chromogenic substrate. Reagent 2: Bovine Factor Xa	Same.
Reagent Form	Liquid reagents	Liquid reagents	Same.
Specimen Type	Citrated human plasma	Citrated human plasma	Same.
Analyzers / Instrumentation	STA R® (K983460), STA Compact® (K093167) and STA Satellite® (K082248) analyzers.	STA R® family analyzers includes STA R® (K983460), STA R® Evolution (K093001) and STA R Max 3 (K212183). STA Compact® (K093167) and STA Satellite® (K082248) analyzers.	Compatible with the same analyzer family; differences do not affect assay performance.
User Environment	Hospital laboratories or other healthcare laboratories	Hospital laboratories or other healthcare laboratories	Same.
Anatomical Site of Use	Not applicable; no direct patient contact	Not applicable; no direct patient contact	Same.
Sterility	Not sterile; sterility not required	Not sterile; sterility not required	Same.
Biocompatibility	Not applicable; no direct patient contact	Not applicable; no direct patient contact	Same.

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510(k) Summary



The proposed STA® Liquid Anti-Xa device has the same intended use, assay methodology, reagent formulation, technological characteristics, and principles of operation as the legally marketed predicate STA®-Liquid Anti-Xa device (K111822), which is cleared for use on the STA R®, STA Compact®, and STA Satellite® analyzer platforms. The STA R Max® 3 analyzer is a member of the STA R® analyzer family and incorporates the same fundamental technology and operating principles as previously cleared family members used with the STA® Liquid Anti-Xa assay.

Performance verification studies conducted on the STA R Max® 3 demonstrated that the assay performs as intended and produces results comparable to those obtained on the predicate analyzer platforms. The data support the conclusion that use of the STA® Liquid Anti-Xa assay on the STA R Max® 3 does not raise new questions of safety or effectiveness and that the proposed device is substantially equivalent to the predicate device with respect to intended use, technological characteristics, clinical performance, and overall functionality.

8. Standards/Guidance Documents Referenced:

- CLSI EP09c (3rd Edition): Measurement Procedure Comparison and Bias Estimation Using Patient Samples.
- WHO / NIBSC International Standards: 6th International Standard Unfractionated Heparin (NIBSC 07/328).
- 3rd International Standard Low Molecular Weight Heparin (NIBSC 11/176).

9. Performance Characteristics

Precision Validation (CLSI EP05-A3): Precision was evaluated in accordance with the recommendations of CLSI EP05-A3. The study was conducted over a 22 day period at two external testing sites, with two runs performed per day. Each sample was tested using two lots of STA®-Liquid Anti-Xa. Testing was performed on one STA R Max® 3 analyzer at each study site. Five spiked plasma sample levels, consisting of three unfractionated heparin (UFH) and three low molecular weight heparin (LMWH) samples spanning the assay measuring range, were tested in duplicate (n=2) during each run, resulting in a total of 352 sample determinations.

Calibration was performed using STA®-Multi-Hep Calibrator, with one calibration replicate per calibration event. Four quality control levels, including STA®-Quality HNF/UFH Levels 2 IU/mL and 7 IU/mL and STA®-Quality HBPM/LMWH Levels 8 IU/mL and 14 IU/mL, were tested once per run.

Precision was estimated by variance component analysis and included the following sources of variability: within-run (repeatability), between-run, between-day, between-lot, and within-laboratory precision. The precision results for each sample, all laboratories combined, are summarized in the table below.

Table 4: Precision Study Results Table: All laboratories, 4 factors nested (site, lot, day and run); N=352 per sample

All laboratories		Samples									
Hybrid calibration	Dedicated calibration	UFH plasmas			LMWH plasmas			UFH QC		LMWH QC	
		1	2	3	4	5	6	7	8	9	10
N		352	352	352	352	352	352	352	352	352	352
Mean	IU/ml	0.20	0.67	0.96	0.82	1.38	1.57	0.24	0.72	0.67	1.29
		0.21	0.66	0.92	0.86	1.43	1.62	0.25	0.70	0.71	1.33
CV	%	6.6	4.8	4.0	3.3	3.6	4.0	7.1	4.1	4.5	4.2
		5.6	4.9	4.6	3.8	4.1	4.4	6.6	3.4	4.3	4.0
Repetability (within-run)	SD	0.009	0.020	0.022	0.018	0.034	0.040	0.011	0.019	0.018	0.033
	(IU/ml)	0.008	0.020	0.023	0.018	0.039	0.040	0.011	0.016	0.019	0.035
	CV	4.5	3.0	2.3	2.2	2.5	2.5	4.6	2.6	2.7	2.6
	(%)	3.8	3.0	2.5	2.1	2.7	2.5	4.4	2.3	2.7	2.6
Reproducibility	SD	0.014	0.038	0.045	0.032	0.058	0.073	0.021	0.032	0.033	0.060
	(IU/ml)	0.013	0.037	0.054	0.037	0.062	0.078	0.021	0.026	0.034	0.058
	CV	7.0	5.7	4.7	3.9	4.2	4.6	8.8	4.4	4.9	4.7
	(%)	6.2	5.6	5.9	4.3	4.3	4.8	8.4	3.7	4.8	4.4
Between-run	SD	0.003	0.005	0.010	0.005	0.015	0.020	0.009	0.140	0.010	0.012
	(IU/ml)	0.000	0.009	0.008	0.004	0.011	0.019	0.013	0.018	0.009	0.023
	CV	1.5	0.7	1.0	0.6	1.1	1.3	3.8	19.4	1.5	0.9
	(%)	0.0	1.4	0.9	0.5	0.8	1.2	5.2	2.6	1.3	1.7
Between-day	SD	0.006	0.000	0.007	0.009	0.015	0.023	0.000	0.004	0.014	0.024
	(IU/ml)	0.006	0.000	0.003	0.014	0.011	0.031	0.000	0.000	0.015	0.015
	CV	3.0	0.0	0.7	1.1	1.1	1.5	0.0	0.6	2.1	1.9
	(%)	2.9	0.0	0.3	1.6	0.8	1.9	0.0	0.0	2.1	1.1
Between lot	SD	0.009	0.023	0.037	0.010	0.007	0.011	0.015	0.016	0.015	0.028
	(IU/ml)	0.008	0.030	0.048	0.023	0.047	0.052	0.012	0.005	0.013	0.026
	CV	4.5	3.4	3.9	1.2	0.5	0.7	6.3	2.2	2.2	2.2
	(%)	3.8	4.5	5.2	2.7	3.3	3.2	4.8	0.7	1.8	2.0
Between lab	SD	0.000	0.023	0.000	0.022	0.041	0.051	0.000	0.015	0.015	0.032
	(IU/ml)	0.000	0.000	0.000	0.015	0.000	0.021	0.000	0.009	0.018	0.026
	CV	0.0	3.4	0.0	2.7	3.0	3.2	0.0	2.1	2.2	2.5
	(%)	0.0	0.0	0.0	1.7	0.0	1.3	0.0	1.3	2.5	2.0

Linearity Validation (CLSI EP06 Ed2): A linearity study was conducted to evaluate the analytical measuring range of the STA®-Liquid Anti-Xa assay on the STA R Max® 3 for both UFH and LMWH applications. Nine concentration levels spanning the claimed measuring ranges were evaluated, extending to approximately 1.40 IU/mL for UFH and 2.40 IU/mL for LMWH. Testing was performed on one STA R Max® 3 analyzer using three lots of STA®-Liquid Anti-Xa

reagent (4 mL and 8 mL presentations), with 10 replicate measurements at each concentration level. Linearity was assessed for the hybrid, dedicated UFH, and dedicated LMWH calibration configurations. Regression analysis demonstrated that observed nonlinearity remained within predefined acceptance criteria throughout the claimed analytical measuring ranges of 0.12 to 1.10 IU/mL for UFH and 0.12 to 2.00 IU/mL for LMWH.

Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ)

The LoB for STA®-Liquid Anti-Xa on the STA R Max® 3 was successfully calculated from measurements of five blank plasma samples (60 replicates per calibration profile). Testing was performed over three days on three STA R Max® 3 analyzers using three reagent lots of STA®-Liquid Anti-Xa and STA®-Multi Hep Calibrator. The LoB for the measurement procedure was set to 0.04 IU/mL for both UFH and LMWH.

The LoD for STA®-Liquid Anti-Xa on the STA R Max® 3 was successfully calculated from measurements of six low-level plasma samples ranging from 0.04 to 0.20 IU/mL (72 replicates per calibration profile). Testing was performed over three days on three STA R Max® 3 analyzers using three reagent lots, with quadruplicate measurements performed in a single daily run. Detection capability was assessed using hybrid, dedicated UFH, and dedicated LMWH calibration profiles. The LoD for the measurement procedure was set to 0.10 IU/mL for both UFH and LMWH.

The LoQ for STA®-Liquid Anti-Xa on the STA R Max® 3 was successfully calculated from measurements of five low-level samples ranging from 0.10 to 0.26 IU/mL. Testing was performed over three days on three STA R Max® 3 analyzers using three reagent lots, with four replicate measurements per sample level per run. A total of 60 results were generated for each sample level and reagent lot. Sample concentrations were verified on both the STA Satellite Max and STA R Max® 3 systems. Reference testing was performed on the STA Satellite Max using STA®-Liquid Anti-Xa reagent and STA®-Multi Hep Calibrator. The LoQ for the measurement procedure was set to 0.12 IU/mL for both UFH and LMWH.

Method comparison (CLSI EP09c): Method comparison (bridging) studies were performed to demonstrate equivalence of STA® Liquid Anti-Xa results obtained on the STA R Max 3 and STA R Evolution analyzers. The study was conducted in accordance with CLSI EP09c, "Measurement Procedure Comparison and Bias Estimation Using Patient Samples."

A total of 138 samples were evaluated, including normal plasma samples, unfractionated heparin (UFH) samples, low molecular weight heparin (LMWH) samples, and contrived samples prepared using WHO international standards.

Each sample was tested in duplicate using one lot of STA® - Liquid Anti-Xa reagent on one STA R Max 3 and one STA -R Evolution analyzer. Data analysis was performed using the first replicate.

Normal Sample Verification (Absence of Heparin)

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510(k) Summary



All 20 normal samples yielded results below the assay detection limit on both analyzers, using hybrid, dedicated UFH and dedicated LMWH calibrations, confirming equivalence in the low (no heparin) range.

Regression Analysis on the heparinized samples

After exclusion of samples outside the analytical measuring range or identified as outliers, 106 samples were included in the final analysis (54 UFH and 52 LMWH) out of the 118 heparinized samples tested.

Regression analysis was performed using regression, based on data characteristics and CLSI EP09c recommendations.

Table 5: Passing Bablok Regression Results

Calibration / Assay	Slope (95% CI)	Intercept (95% CI) IU/mL	Correlation Coefficient (r)
Anti-Xa (Hybrid calibration)	1.00 (0.99 to 1.02)	-0.01 (-0.02 to 0.00)	0.996
Anti-Xa (Dedicated UFH)	1.03 (1.00 to 1.05)	-0.02 (-0.03 to 0.00)	0.989
Anti-Xa (Dedicated LMWH)	1.00 (0.97 to 1.02)	-0.02 (-0.03 to 0.01)	0.996

All regression parameters met the predefined acceptance criteria: slope within 0.90–1.10, intercept within 0.00 ± 0.10 IU/mL and $r \geq 0.950$.

Analysis of Bias at Specific Levels

Bias was calculated at clinically relevant Anti-Xa concentrations using the Passing Bablok regression equations.

The calculated biases met all predefined acceptance criteria for absolute and relative bias for all calibrations.

The validation data demonstrate that the instrument hardware differences introduce no new issues of safety or effectiveness regarding assay precision, linearity, detection capabilities and method comparison study fully supporting a determination of substantial equivalence.

10. Conclusion

This Special 510(k) submission supports the use of the FDA-cleared STA® Liquid Anti-Xa assay on the FDA-cleared STA R Max® 3 analyzer. The STA R Max® 3 is part of an instrument family that includes analyzers previously cleared for use with the STA® Liquid Anti-Xa assay. No changes are being made to the assay itself; this submission is intended to extend compatibility to an additional analyzer within the cleared instrument family.

Based on the substantial equivalence comparison and the validation data demonstrating comparable analytical performance on the STA R Max 3 analyzer, the proposed STA® Liquid



Anti-Xa device was shown to be substantially equivalent to the cleared and currently marketed predicate device, STA® Liquid Anti-Xa (K111822).

The proposed device has the same intended use, assay methodology, reagent composition, technological characteristics, and principles of operation as the predicate device. Any differences (addition of STA R Max 3 analyzer) between the subject and predicate devices do not affect the safety or effectiveness of the system. The STA® Liquid Anti-Xa device provides equivalent analytical performance and maintains the same clinical utility and overall functionality as the predicate device when used on the STA R Max 3 analyzer.

Assay Cut-off

Not applicable

Clinical Studies

Clinical Sensitivity

Not applicable

Clinical Specificity

Not applicable

Clinical Cut-off

Not applicable

Reference Interval

Not applicable