510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

K082248

B. Purpose for Submission:

Clearance of a modified cleared device

C. Manufacturer and Instrument Name:

Diagnostica Stago STA Satellite™ Automated Multi-Parametric Analyzer

D. Type of Test or Tests Performed:

Coagulation

E. System Descriptions:

1. Device Description:

   The DSI STA Satellite™ is a fully automated bench-top system. Samples and test reagents are loaded into the instrument where sample handling, reagent delivery, analysis, and reporting or results are performed automatically.

   The STA Satellite™ System consists of a cuvette, which holds patient sample and any needed reagent ; a metal ball located in the cuvette that oscilates to measure coagulation ; a needle that aspirates and dispenses sample and reagent into the cuvette ; a camera to measure coagulation by chronometric method ; a light source and sensor to transmit light through the cuvette and subsequently measure the light absorbed; and application software.

2. Principles of Operation:

   The STA Satellite™ system uses the well established photometric and chronometric methods of detection. The photometric measurement is based on measured absorbance of monochromatic light passing through the cuvette as clotting takes place. The chronometric method consists of measuring variation of the oscillation amplitude of the metal ball in the sample cuvette. A decrease in amplitude corresponds to coagulation.

3. Modes of Operation:

Automated, Random access, Stat

4. Specimen Identification:

   Specimens are identified by barcode and rack position.

5. Specimen Sampling and Handling:

   Centrifuged, open tube samples are loaded onto a sample carousel. Tubes are sampled by the instrument and loaded into the appropriate cuvette for assaying.

6. Calibration:

   The STA Satellite™ automatically requires calibration for each lot of reagents used. The calibration can be automatically validated if calibration controls are used (user must define two control plasmas) or manually validated if control values are outside the acceptable range.

7. Quality Control:

   QC for each test is mandatory. User can use up to three control plasmas, one of which must be defined. Control values outside a pre-determined range are flagged by the system.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes___X____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 864.5425

2. Classification:

   Class II

3 Product code:

   JPA

4. Panel:

81 Hematology

G. Intended Use:

1. Indication(s) for Use:

   The STA Satellite™ Automate 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.

2. Special Conditions for Use Statement(s):

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   Diagnostica Stago STA-R ® Automated Multi-Parametric Analyzer (K983460)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	An automated clinical instrument for the performance of tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in the monitoring anticoagulant therapy.	same
Principle of Operation	Photometric and chronometric	same

Differences		
Item	Device	Predicate
Technological characteristics	Chronometric detection method of a photo-optical detection	Chronometric detection of a mechanical detection system
Architecture	Bench top	Floor model

I. Special Control/Guidance Document Referenced (if applicable):

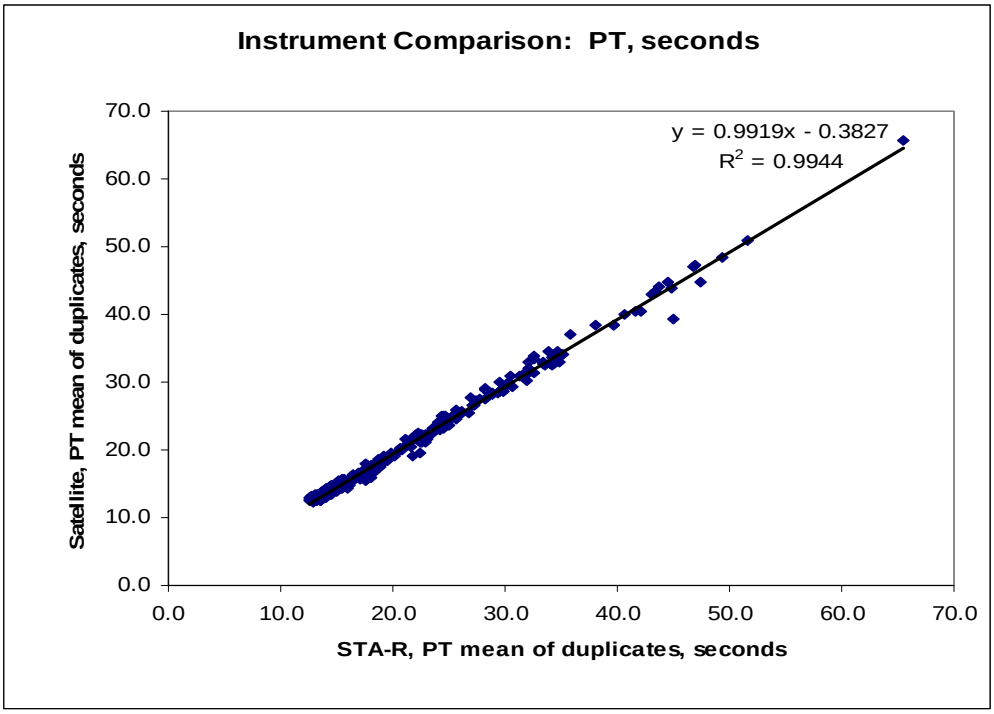
J. Performance Characteristics*:*

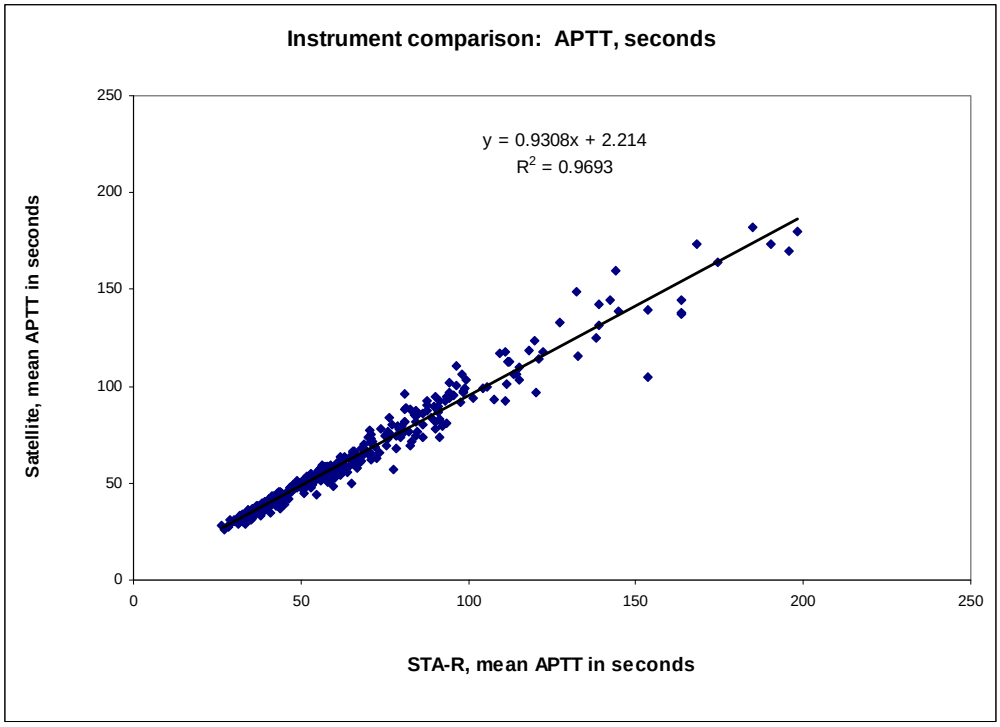
1. Analytical Performance:

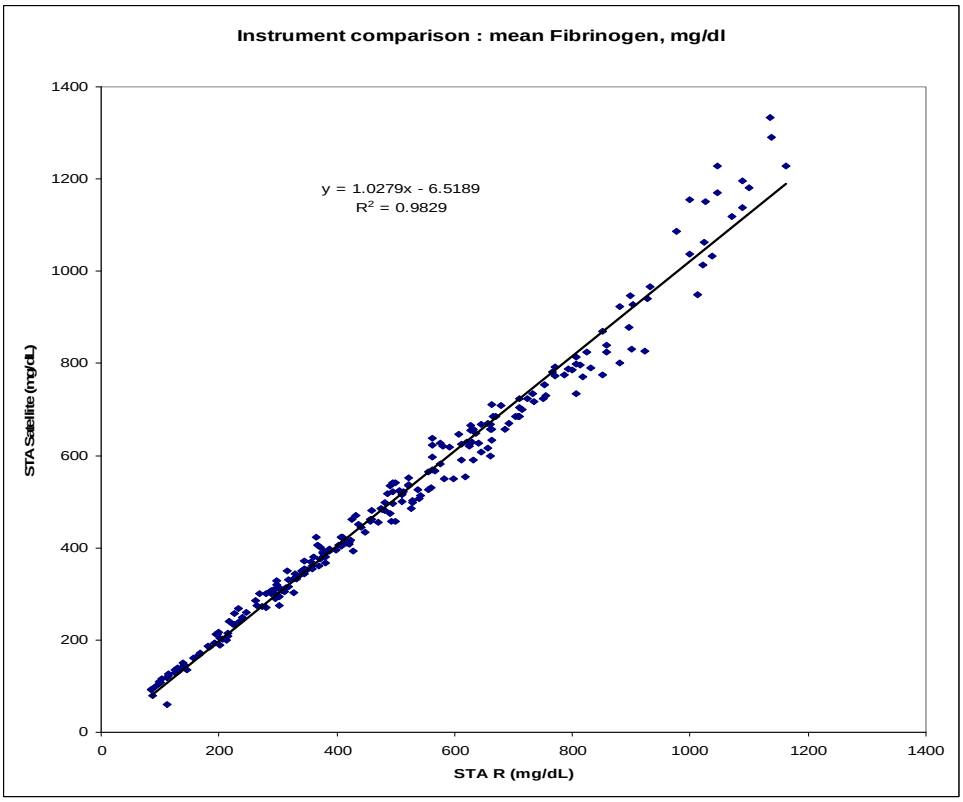
   a. Accuracy:

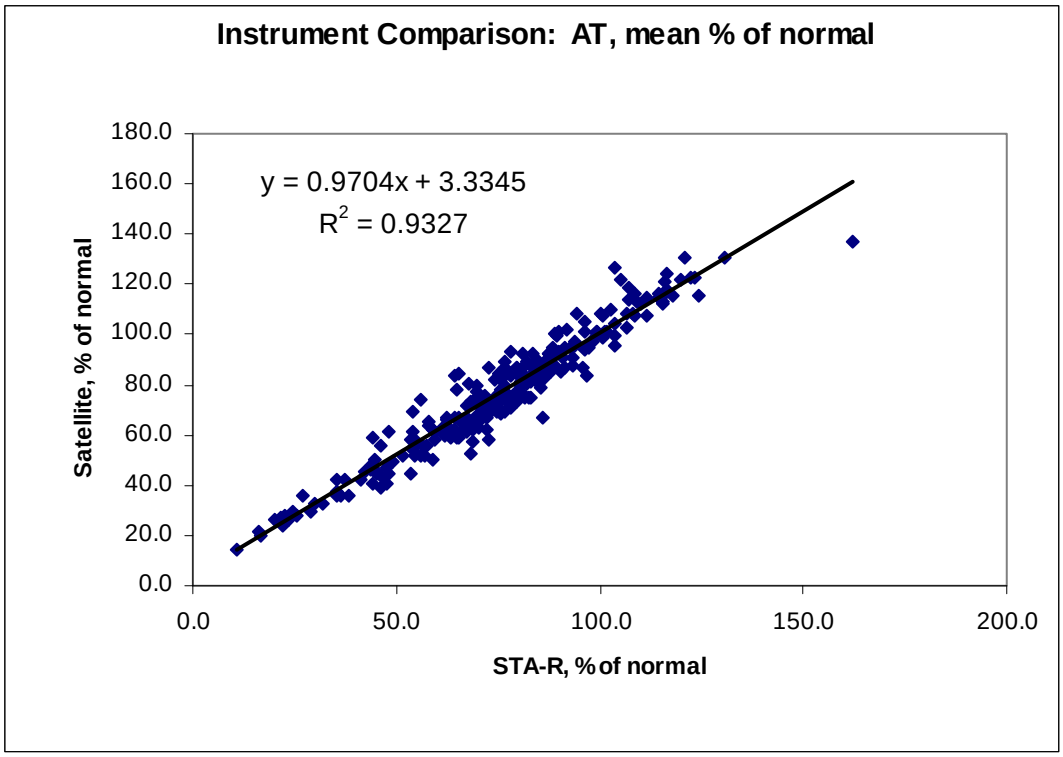
   Data comparing the STA Satellite™ was collected at 3 sites- 2 foreign sites (one being the manufactures site) and 1 US site. Samples were obtained from liver disease patients, patients on Coumadin therapy, unfractionated heparin (UFH) and low molecular weight heparin (LMWH) therapy and normal outpatients.

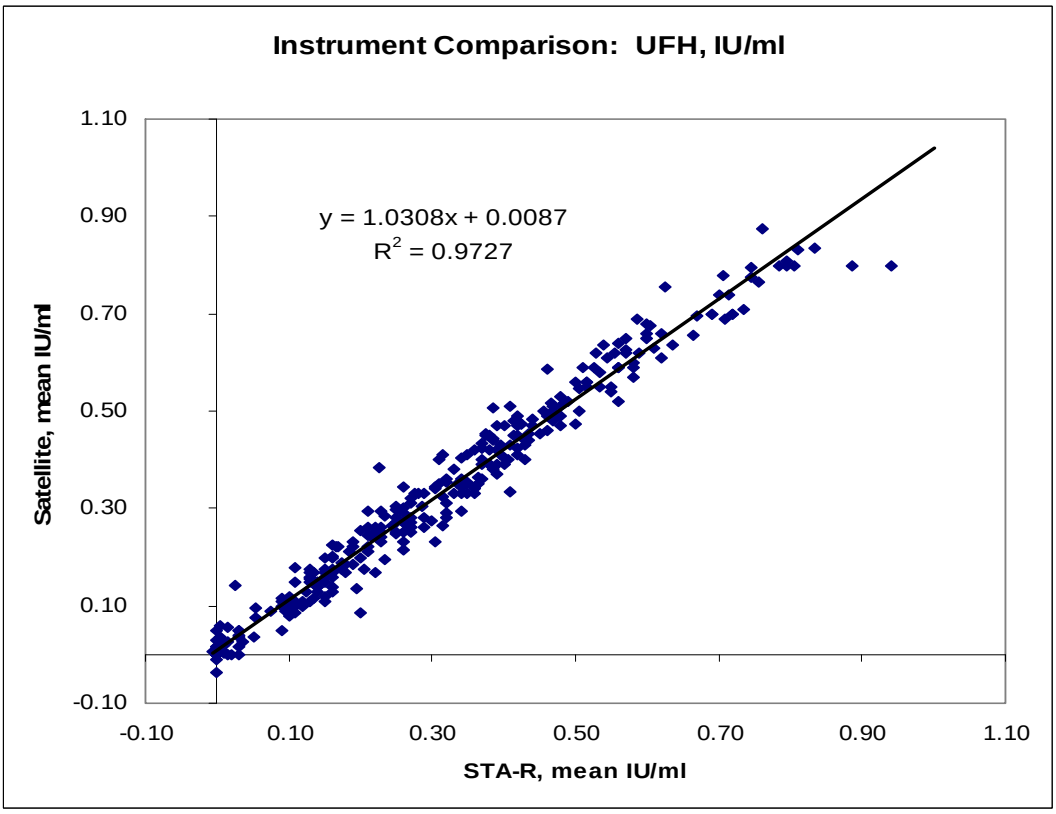
   Data was presented by site and pooled. Initial testing at the US site did not meet acceptance criteria. Routine preventive maintenance was performed and testing repeated which produced acceptable results.

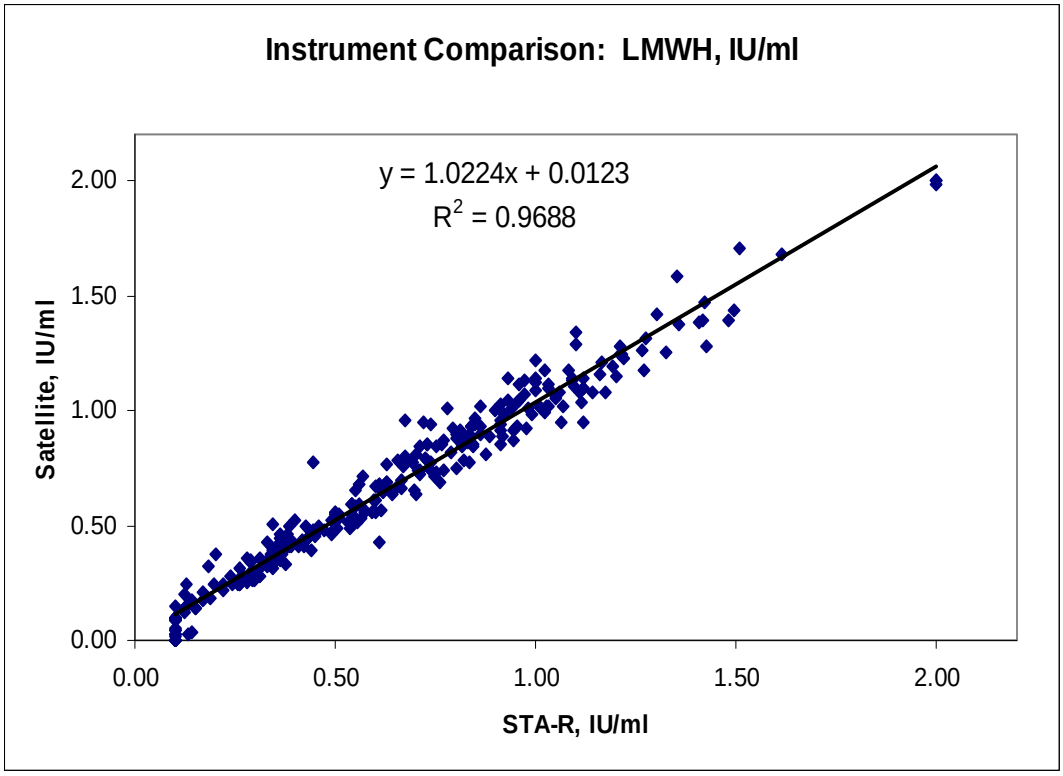


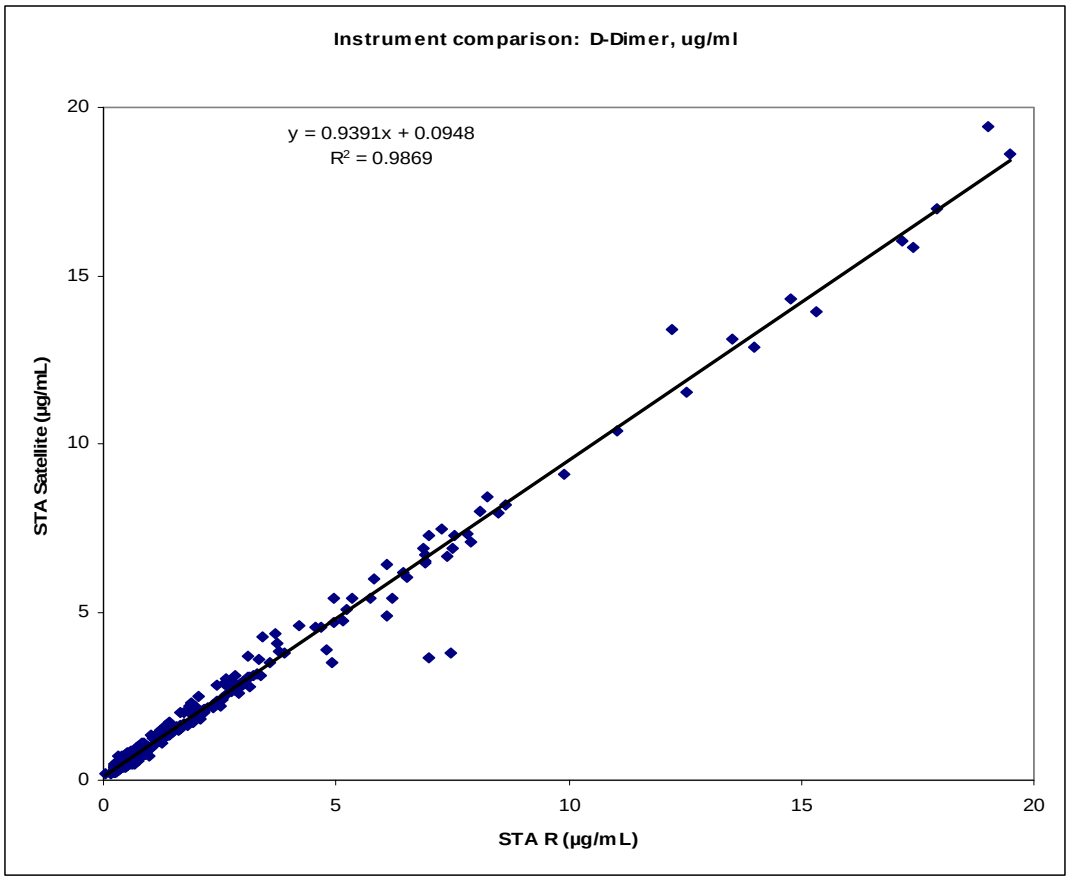

Instrument comparison: APTT, seconds
y = 0.9308x + 2.214
R2 = 0.9693
Satellite, mean APTT in seconds
STA-R, mean APTT in seconds
0
50
100
150
200
250


Instrument comparison : mean Fibrinogen, mg/dl
y = 1.0279x - 6.5189
R2 = 0.9829
STA Satellite (mg/dL)
STA R (mg/dL)
0
200
400
600
800
1000
1200
1400


Instrument Comparison: AT, mean % of normal
y = 0.9704x + 3.3345
R2 = 0.9327
Satellite, % of normal
STA-R, % of normal
180.0
160.0
140.0
120.0
100.0
80.0
60.0
40.0
20.0
0.0
0.0
50.0
100.0
150.0
200.0


Instrument Comparison: UFH, IU/ml
y = 1.0308x + 0.0087
R2 = 0.9727
Satellite, mean IU/ml
STA-R, mean IU/ml
1.10
0.90
0.70
0.50
0.30
0.10
-0.10
-0.10
0.10
0.30
0.50
0.70
0.90
1.10


Instrument Comparison: LMWH, IU/ml
y = 1.0224x + 0.0123
R2 = 0.9688
Satellite, IU/ml
STA-R, IU/ml
0.00
0.50
1.00
1.50
2.00



b. Precision/Reproducibility:

Within-run precision was evaluated on 21 single tests using the following controls: STA® Coag N + ABN (PT< APTT> Fibrinogen), STA® System Control P (AT III), STA® Heparin control (UFH), STA®Quality LMWH (LMWH) and STA® Liatest Control (D-Dimer). Precision was assessed on three instruments.

Statistical Summary of the STA-Satellite® Intra-run Precision

	Mean	**Std Dev**	**C.V.**	**95% CI**
PT Normal	13.71	0.14	1.06	13.28 – 14.15
PT Abnormal	21.46	0.3	1.40	20.55 – 22.36
APTT Normal	35.25	0.16	0.45	34.78 – 35.72
APTT Abnormal	54.39	0.41	0.75	53.16 – 55.61

Fibrinogen Normal	326.86	11.17	3.42	293.36 – 360.35
Fibrinogen Abnormal	106.06	4.71	4.44	91.92 – 120.21
AT Normal	97.56	1.67	1.72	92.54 – 102.57
AT Abnormal	43.49	0.72	1.65	41.35 – 45.64
UFH Normal	0.28	0.01	4.95	0.24 – 0.32
UFH Abnormal	0.57	0.01	2.23	0.53 – 0.60
LMWH Normal	0.74	0.03	3.58	0.66 – 0.82
LMWH Abnormal	1.45	0.06	4.15	1.27 – 1.63
D-Dimer Normal	.24	0.04	17.36	0.11 – 0.36
D-Dimer Abnormal	2.08	0.05	2.27	1.93 – 2.22

Inter-run (day-to-day) precision was evaluated on n≥ 20 days with the results of the daily controls: STA® Coag N + ABN (PT< APTT> Fibrinogen), STA® System Control P (AT III), STA® Heparin control (UFH), STA®Quality LMWH (LMWH) and STA® Liatest Control (D-Dimer).

	Mean	**Std Dev**	**C.V.**	**95% CI**
PT Normal	13.93	0.20	1.45	13.32 – 14.53
PT Abnormal	20.99	0.25	1.20	20.23 – 21.74
APTT Normal	33.92	0.39	1.15	32.75 – 35.09
APTT Abnormal	55.25	1.16	2.11	51.76 – 58.75
Fibrinogen Normal	337.00	9.98	2.96	307.06 – 366.94
Fibrinogen Abnormal	115.07	3.05	2.65	105.92 - 124.22
AT Normal	109.43	2.85	2.60	100.89 – 117.98
AT Abnormal	44.70	2.74	6.14	36.47 – 52.93
UFH Normal	0.29	0.01	4.72	0.25 – 0.33

UFH Abnormal	0.58	0.02	3.00	0.53 – 0.63
LMWH Normal	0.75	0.02	3.26	0.68 – 0.82
LMWH Abnormal	1.45	0.06	4.18	1.27 – 1.63

c. *Linearity*:

A Fibrinogen reportable range of 150-900 mg/dl was demonstrated by testing 13 samples containing fibrinogen from 140 to 1040 mg/dl, on two STA Satellite® analyzers. Percent recovery (STA Satellite value/expected value x 100%) varied from 94 – 105 % across the range of values.

An ATIII reportable range of up to 140% for the photometric ATIII assay was demonstrated by testing 13 samples containing 0 to 153% ATIII, on two STA Satellite® analyzers. Percent recovery (STA Satellite value/expected value x 100%) varied from 84 – 105 % across the range of values.

Unfractionated Heparin (UFH) linearity of up to 0.70 anti-Xa IU/ml for the UFH assay was demonstrated by testing 13 samples containing 0 to 0.75 IU/ml UFH, on two STA Satellite® analyzers. Percent recovery (STA Satellite value/expected value x 100%) varied from 89 to 110%.

A D-Dimer reportable range of 0.0 -4.0 µg/ml was demonstrated by testing 14 samples containing from 0 -4 µg/ml of d-dimer, on two STA Satellite® analyzers. Percent recovery (STA Satellite value/expected value x 100%) varied from 93 – 105 % across the range of values.

Low Molecular Weight Heparin (LMWH) linearity of up to 2.0 anti-Xa IU/ml was demonstrated by testing samples containing 0 to 2.40 anti-Xa IU/ml of LMWH on two STA Satellite® analyzers. Percent recovery (STA Satellite value/expected value x 100%) varied from 92 to 103%.

d. *Carryover*:

Sample to sample carry-over was evaluated on three STA Satellite™ analyzers. A normal human plasma pool was prepared and divided into two portions. 10 IU of UFH was added to one portion which caused the APTT value to be >100 secs. The heparinized pool was tested five times followed by the normal pool. This cycle was repeated five times. The APTT values of the normal pool remained unaffected by the heparinized pool, demonstrating the lack of sample-to-sample carryover.

e. *Interfering Substances*:

N/A

2. Other Supportive Instrument Performance Data Not Covered Above:

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

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