

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

A. 510(k) Number:

K031377

B. Instrument Name:

Sysmex® Automated Coagulation Analyzer CA-500 (series)

C. System Descriptions:

1. Modes of Operation:

Random access of up to 5 parameters, open tube, STAT

2. Software:

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

Yes _____ x _____ or No _____

3. Sample Identification:

Manually with the numeric key and analysis parameter keys, gaining ID Nos. and analysis parameters collectively from the host computer. Manually entering ID Nos. so that analysis orders will be automatically received from the host computer using ID nos. that have been read with the optional bar code scanner so that analysis order information will be automatically received from the host computer

4. Specimen Sampling and Handling:

The incubation pipette on the instrument detects sample surface, aspirates a sample from an open tube and dispenses it out into a reaction tube in the reaction tube rack.

5. Assay Types:

The instrument is capable of running the following coagulation assays: prothrombin time activated partial thromboplastin time, fibrinogen, d-dimer, antithrombin III, and thrombin time.

6. Reaction Types:

Chromogenic (Antithrombin III), clotting (PT, APTT, Fibrinogen, Thrombin Time) and immunological (d-dimer)

7. Calibration:

The instrument uses standard commercial plasma material to plot standard curves

8. Quality Control:

2 QC programs are available. A Mean control that uses the average data of 2 consecutive analysis made on a QC sample (Commercial control plasma or pooled plasma), and a L-J control that uses data of a single analysis on a QC sample.

D. Other Supportive Performance Characteristics Data Not Covered In The “L. Performance Characteristics” Section Of The SE Decision Summary.

Test	Predicate Device	CA-500 Model	N	Coefficient of Correlation	Regression Equation
D-Dimer (Advanced D-Dimer)	CA-7000	CA-560	390	0.992	$Y=1.01X +0.14$
PT, secs (Thromborel® S)	CA-6000	CA-560	248	0.999	$Y=1.00X -0.50$
PT, INR (Thromborel® S)	CA-6000	CA-560	248	0.999	$Y=0.89X +0.11$
Derived Fibrinogen (Thromborel® S)	CA-6000	CA-560	248	0.998	$Y=1.08X +0.04$
PT, secs (Innovin®)	CA-6000	CA-560	243	0.999	$Y=1.03X -0.26$
PT, INR (Innovin®)	CA-6000	CA-560	243	0.999	$Y=1.08X -0.09$
Derived Fibrinogen (Innovin®)	CA-6000	CA-560	247	0.995	$Y=1.09X -0.17$
PT, secs (Thromboplastin C Plus)	CA-6000	CA-560	245	0.997	$Y=1.00X -0.20$
PT, INR (Thromboplastin C Plus)	CA-6000	CA-560	245	0.998	$Y=1.00X -0.00$
Derived Fibrinogen (Thromboplastin C Plus)	CA-6000	CA-560	245	0.998	$Y=1.12X +0.03$
APTT (Actin®)	CA-6000	CA-540	864	0.982	$Y=1.00X -0.20$
APTT (Actin® FS)	CA-6000	CA-540	857	0.983	$Y=1.00X +0.10$
APTT (Actin® FSL)	CA-6000	CA-540	864	0.990	$Y=1.00X +0.10$

E. Other Supportive Information:

Within run, between run and total %CV demonstrated acceptable performance (<5%)
 Software verification and validation data
 Carryover studies
 Interference Studies
 Reportable Ranges

F. Conclusion:

All studies demonstrated acceptable performance. I recommend that the device is found substantially equivalent to a legally marketed device.