510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k110212

B. Purpose for Submission:
Clearance of the INRatio®2 PT/INR Monitoring System for professional use, prescription home use patient self-testing and test strip modification

C. Measurand:
Prothrombin Time and INR

D. Type of Test:
Clotting Assay

E. Applicant:
Alere San Diego, Inc.

F. Proprietary and Established Names:
Alere INRatio®2 PT/INR Monitoring System (Professional Use)
Alere INRatio®2 PT/INR Home Monitoring System
Alere INRatio®2 PT/INR Test Strip

G. Regulatory Information:
1. Regulation section:
   21 CFR § 864.7750 - Prothrombin Time Test
2. Classification:
   Class II
3. Product code:
   GJS - Prothrombin Time Test
4. Panel:
   Hematology (81)

H. Intended Use:
1. Intended use(s):
   Alere INRatio®2 PT/INR Monitoring System (Professional Use): The Alere INRatio®2 PT/INR Monitoring System (Professional Use), consisting of the INRatio®2 Monitor and INRatio®2 PT/INR test strip, is used for quantitative determination of international normalized ratio (INR) in fresh capillary whole blood to monitor the effect of warfarin on clotting time by health care professionals. The Alere INRatio®2 PT/INR Monitoring System (Professional Use) is intended for use outside of the body (in vitro diagnostic use). The Alere INRatio®2 PT/INR Monitoring System (Professional Use) is not intended to be used for screening purposes.

   Limitations: The Alere INRatio®2 PT/INR Monitoring System (Professional Use) is not intended for use in patients who are transitioning from heparin treatment to warfarin

therapy.

Alere INRatio®2 PT/INR Home Monitoring System: The Alere INRatio®2 PT/INR Home Monitoring System, consisting of the INRatio®2 Home Monitor and INRatio®2 PT/INR test strip, is used for quantitative determination of international normalized ratio (INR) in fresh capillary whole blood to monitor the effect of warfarin therapy on clotting time by properly selected suitably trained users (by prescription for home use or other order of a treating physician). Patients must be stabilized (>6 weeks) on warfarin therapy. The Alere INRatio®2 PT/INR Home Monitoring System is intended for use outside of the body (in vitro diagnostic use). The Alere INRatio®2 PT/INR Home Monitoring System is not intended to be used for screening purposes.

Limitations: The Alere INRatio®2 PT/INR Home Monitoring System is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.

2. Indication(s) for use:
   Same as Intended Use
3. Special conditions for use statement(s):
   Prescription Use only
   Professional Use
   Prescription Home Use
4. Special instrument requirements:
   INRatio®2 Monitor

I. Device Description:

The INRatio®2 PT/INR Monitoring Systems (Professional and Home Use) perform a modified version of the one-stage Prothrombin Time (PT) test, using commercially available recombinant human thromboplastin (rhTP) reagent. The system consists of a monitor and disposable test strips. An International Normalized Ratio (INR) value is calculated from measured PT and the INR is displayed on the monitor to the user/patient.

J. Substantial Equivalence Information:

1. Predicate device name(s) and Predicate 510(k) number(s):
   a. INRatio® PT Monitoring System, k020679 & k021923
   b. INRatio®2 PT/INR Monitoring System, k072727
   c. INRatio® PT/INR Test Strip, k092987

2. Comparison with predicate:

Similarities		
Item	Device INRatio®2 PT/INR Monitoring System utilizing modified Alere™ INRatio®2 PT/INR Test Strip (k110212)	Predicate INRatio® /INRatio®2 PT/INR Monitoring Test Systems utilizing INRatio® PT/INR Test Strip (k020679, k021923, k072727, k092987)
Intended Use	An in vitro diagnostic test system for quantitative determination of international normalized ratio (INR) in fresh capillary whole blood to monitor the effect of warfarin on clotting time. It is not intended to be used for screening purposes. Professional use: Used by health care professionals. Home use: Used by properly selected suitably trained users (by prescription for home use or other order of a treating physician). Patients must be stabilized (>6 weeks) on warfarin therapy. The following limitation statement is to be included for both professional and home use: Limitations: The Alere INRatio®2 PT/INR Home Monitoring System is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.	An in vitro diagnostic test system for quantitative determination of international normalized ratio (INR) in fresh capillary whole blood to monitor the effect of warfarin on clotting time. It is not intended to be used for screening purposes. Professional use: The INRatio® /INRatio®2 PT/INR Monitoring System is intended for professional use for monitoring people taking warfarin and other oral anticoagulant (blood thinning) therapy. Home use: The INRatio® PT/INR Monitoring System is intended for home use by people taking warfarin and other oral anticoagulant (blood thinning) therapy who need to monitor the clotting time of their blood.
Intended Sample	Capillary whole blood	Same
Mode of Measurement	Electrical Impedance	Same
Number of Reaction Sites (and pairs of electrodes)	3 (3 pairs of electrodes)	Same
Test Strip Layout	"Trident"	Same
Quality Control	Integrated in test strip High QC (therapeutic range) Low QC (normal range)	Same
Test Time	Approximately 1 minute for INRatio®2	Same
Measurement Range	INR: 0.7 - 7.5	INR: 0.7 - 7.5 PT: 7 - 75 sec
Accuracy	Slope = 0.9 – 1.1 Intercept ± 0.5 INR	Same
Strip Calibration	Per WHO889:1999, using normal and therapeutic capillary whole blood samples	Same

Similarities		
Item	Device INRatio®2 PT/INR Monitoring System utilizing modified Alere™ INRatio®2 PT/INR Test Strip (k110212)	Predicate INRatio® /INRatio®2 PT/INR Monitoring Test Systems utilizing INRatio® PT/INR Test Strip (k020679, k021923, k072727, k092987)
	vs. reference method using normal and therapeutic venous whole blood samples processed to plasma	
Strip storage conditions	Below 90°F (32°C) until expiration date	Same
Strip warm-up time	5 min at RT, if stored refrigerated	Same
Strip Stability	10 minutes out of pouch	Same

Differences		
Item	Device INRatio®2 PT/INR Monitoring System utilizing modified Alere™ INRatio®2 PT/INR Test Strip (k110212)	Predicate INRatio® /INRatio®2 PT/INR Monitoring Test Systems utilizing INRatio® PT/INR Test Strip (k020679, k021923, k072727, k092987)
Test Strip Graphics	Product name – INRatio2 Thumbprint with directional leading arrow	Product name - INRatio
Minimum Sample Volume	9.5 µL	15 µL
Reference Range	INR: 0.8 – 1.3	INR: 0.7 - 1.2 PT: 6.5 - 11.9 sec
Precision (Repeatability)	Normal subjects Capillary %CV - 8.2% Therapeutic Capillary %CV - 6.2% Therapeutic Patient Self Testers Capillary %CV - 5.7%	Normal subjects Capillary %CV - 7.6% Therapeutic Capillary %CV - 5.9%
Interfering Factors: Bilirubin Hemoglobin/Hemolysis Lipemia/triglycerides	 None up to 30 mg/dL None up to 1000 mg/dL None up to 1500 mg/dL	 None up to 20 mg/dL None up to 500 mg/dL None up to 1500 mg/dL
Factor Sensitivity: Factor II Factor V Factor VII Factor X	 <56% of normal factor level <62% of normal factor level <78% of normal factor level <74% of normal factor level	 <49% of normal factor level <61% of normal factor level <74% of normal factor level <72% of normal factor level
Hematocrit range	25 – 53%	30 - 55%
Operating conditions: Temperature Humidity	 10 - 32°C (50 - 90°F) 15% - 90% RH	 10 - 35°C (50 - 95°F) 10% - 95% RH
Refrigerated test strip	35-50°F (2-10°C) until expiration date	35-45°F (2-8°C) until expiration

Differences		
Item	Device INRatio®2 PT/INR Monitoring System utilizing modified Alere™ INRatio®2 PT/INR Test Strip (k110212)	Predicate INRatio® /INRatio®2 PT/INR Monitoring Test Systems utilizing INRatio® PT/INR Test Strip (k020679, k021923, k072727, k092987)
storage conditions		date
Strip Stability: Pouched	11 months at recommended storage conditions	15 months at recommended storage conditions

K. Standard/Guidance Document referenced (if applicable):

ISO 17593:2007(E) Clinical laboratory testing and in vitro medical devices - Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy

CLSI C28-P3 - Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Proposed Guideline – Third Edition (Section 8 only)

CLSI EP5-A2 - Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition

CLSI EP7-A - Interference Testing in Clinical Chemistry; Approved Guideline

CLSI H47-A2 - One Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline - Second Edition

CLSI H49-A - Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline

L. Test Principle:

After a drop of fresh capillary whole blood is applied to the sample well of the test strip, it is drawn into the reaction area by capillary action where it mixes with the reagents that initiate coagulation. Initially the impedance across the electrode (measured by the monitor) is high until the air gap is closed by filling the reaction area with blood. As the reaction progresses, the electrical impedance increases and then gradually drops to a second minimum as the clotting reaction proceeds. A characteristic inflection point, identified by the system algorithm is defined as the clotting endpoint. The elapsed time, in seconds, from the initiation of the reaction until the endpoint is reached is the prothrombin time. The monitor software calculates the INR of the sample from the PT using calibration coefficients determined from the strip code.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

   Precision (repeatability) was evaluated with duplicate samples of capillary whole blood. Three lots of the INRatio®2 PT/INR Test Strips were used on both INRatio® and INRatio®2 monitors for the study. For each lot, samples from individuals not receiving warfarin/vitamin K antagonist therapy (Normals, N), (n=118) and samples from subjects on warfarin/VKA therapy (Therapeutics, T), (n=210) were included. The precision performance of the test strips used met the acceptance criteria as shown in the table below:

Interval	Result	Acceptance Criteria
Normal (<2.0 INR)	8.0% CV	CV ≤ 11%
Therapeutic Range (2.0 - 4.5 INR)	5.4% CV	CV ≤ 10%

b. Linearity/assay reportable range:

The study was conducted to verify linearity of the INR range (0.7 to 7.5) of the INRatio®2 PT/INR Test Strips used in conjunction with both INRatio® and INRatio®2 monitors compared to the Sysmex CA-560 laboratory reference method. Seventeen (17) contrived plasma samples were prepared by mixing normal plasma with commercially obtained factor II deficient plasma. Saline-washed normal red blood cells and calcium were added to contrive whole blood of various INRs. One representative strip lot was used for this study. For each sample, 8 replicates were tested on each meter type. In addition, fingerstick capillary whole blood from 2 subjects was also included in the study (8 replicates for each subject) for comparison to the contrived samples. The test strips tested on both INRatio® and INRatio®2 monitors demonstrated accuracy as assessed with respect to percent of results within the Allowable Difference for INR within the reportable range of the system. The observed slope and correlation fall within acceptable ranges.

	INRatio®2	Acceptance Criteria
Observed INR Range	0.7 – 7.5	
% Results within Allowable Difference (INR ≤ 2 and INR 2.0 to 4.5)	100%	To be acceptable, ≥90% of all of the valid tests must fall within the following Allowable Difference criteria: ± 0.5 of reference value for INR less than 2.0 ± 30% of reference value for INR 2.0 to 4.5
Slope	1.00	1 ± 0.3
R Value	0.99	R ≥ 0.85

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

A study was conducted to verify shelf life stability of the INRatio®2 PT/INR Test Strips. Three (3) lots of the INRatio®2 PT/INR Test Strips were used. The strips were incubated at three (3) storage conditions (32±2ºC, 22±2ºC and 4±2ºC) and tested at the various time intervals (3, 6, 8, 9, 10, 12, 13 and 14 months). Testing was conducted with blood from 4 subjects (1 N and 3 T) in 13 replicates per sample for a total of 52 tests. The strips were tested on the INRatio®2 monitor and the results were compared to results on the Sysmex CA-560 reference method. All 3 lots of test strips met stability acceptance criteria requirements up to 12 months for all storage temperatures tested.

d. Detection limit:

Contrived coagulation factor deficient blood samples were prepared by mixing commercially obtained citrated factor deficient plasma in various proportions with normal citrated plasma and with red blood cells such that whole blood samples with several factor concentrations were generated. The factor deficient plasma was used to make whole blood samples in final concentrations of normal plasma from 100% to

0% in 10% intervals. The results of the INRatio®2 and the Sysmex CA-560 were compared. The study verifies Factor sensitivity for the INRatio®2 monitor and INRatio®2 PT/INR Test Strips at the following levels (% of normal factor level; in vitro testing): Factor II<56%; Factor V <62%; Factor VII <78%; and Factor X <74%.

e. Analytical specificity:

A study was conducted to verify the endogenous substances (bilirubin, triglycerides and hemoglobin) at the concentrations present in whole blood do not cause interference with INR results for tests performed with the INRatio®2 PT/INR Test Strips when used in conjunction with the INRatio®2 monitor. Three to four concentrations of each substance was spiked into the iced venous blood of one normal donor blood sample and one therapeutic donor blood sample (INR 2.0- 4.5). Each endogenous substance, at each defined concentration, was tested with a replicated set of at least 48 blood samples using one lot of the INRatio®2 PT/INR Test Strips. Test results from blood samples with and without the endogenous substance on the INRatio®2 monitor were compared to results evaluated from citrated venous blood processed to plasma on the Sysmex CA-560 as the reference method. For all subjects, results fell within the acceptance criteria based on ISO 17593:2007. The study results show that the following substances do not interfere with test results up to the concentrations shown:

Substance	Concentration
Bilirubin	up to 30 mg/dL
Triglycerides (lipemia)	up to 1500 mg/dL
Hemoglobin (hemolysis)	up to 1000 mg/dL

In addition, a study was conducted to characterize the levels of other pharmaceuticals: clopidogrel (active ingredient in Plavix®), acetylsalicylic acid (active ingredient in aspirin), Arixtra (fondaparinux) and atorvastatin (active ingredient in Lipitor®), that might be present for subjects on warfarin/VKA therapy without adverse effects on accuracy of the system. Two concentrations of each substance were spiked into the iced venous blood of normal donor blood samples and therapeutic donor blood samples (INR 2.0- 4.5). Each exogenous substance was tested with a replicated set of at least 48 blood samples using one lot of the INRatio®2 PT/INR Test Strips. Test results from blood samples with and without the exogenous substance on the INRatio®2 monitor were compared to result evaluated from citrated venous blood processed to plasma on the Sysmex CA-560 as the reference method. For all subjects, results fell within the acceptance criteria based on ISO 17593:2007. The study results show that the drugs listed below do not interfere with test results when spiked into whole blood, up to the concentrations shown:

Drug	Up to this concentration
Fondaparinux	up to 5 mg/L
Acetylsalicylic acid	up to 4 mmol/L
Clopidogrel	up to 20 mg/dL
Atorvastatin	up to 600 μg/L
Unfractionated Heparin	up to 2 Units/mL plasma
Low Molecular Weight Heparin	up to 3 Units/mL plasma

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
Accuracy was evaluated with the INRatio®2 PT/INR Test Strips in conjunction with both INRatio® and INRatio®2 monitors with capillary whole blood. Samples from individuals not receiving warfarin/vitamin K antagonist therapy (Normals, INR <2.0), (n=174) and samples from subjects on warfarin/VKA therapy (Therapeutics, INR 2.0 to 4.5), (n=224) were included. Three (3) lots of INRatio®2 PT/INR Test Strips were used for this study. Test results on both monitors were compared to reference results on the Sysmex CA-560 method from citrated venous blood processed to plasma. Linear regression was performed and the Pearson correlation (R value), slope (with confidence interval), and intercept (with confidence interval) were calculated, and Allowable Difference limits were constructed. To pass acceptance criteria, 90% of data for INR ≤ 4.5 must fall within the limits of Allowable Difference.

The results of the study show that each of the 3 strip lots met the acceptance criteria for INR accuracy as represented by % Allowable Difference relative to the Sysmex CA-560 reference method, both below and at therapeutic ranges (<2.0 and 2.0 to 4.5) when analyzed on either INRatio® or INRatio®2 monitors. The data show that 98% of valid test results for the test strips used in conjunction with both monitors are within the Allowable Difference for INR ≤ 4.5. For INR < 2.0, the Allowable Difference is ± 0.5 INR and for INR between 2.0 to 4.5, the Allowable Difference is a % relative INR difference of ± 30%.

Accuracy Data Summary

	INRatio®2	INRatio®	Pooled INRatio®/INRatio®2
INR < 2.0	n = 86	n = 88	n = 174
INR Difference within ± 0.5	98% PASS	99% PASS	98% PASS
Mean INR Difference	-0.05	-0.10	-0.08
INR 2.0 to 4.5	n = 112	n = 112	n=224
Relative INR Difference within ± 30%	97% PASS	98% PASS	98% PASS
Mean INR Difference	0.13	0.12	0.13
Slope	1.09 ± 0.038	1.06 ± 0.037	1.07 ± 0.026
Intercept	0.146 ± 0.097	0.125 ± 0.094	0.135 ± 0.068
R Correlation	0.97	0.97	0.97

b. Matrix comparison:
Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:
Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Health Care Professionals (HCP)
Accuracy: A multi-center study was conducted at four (4) external clinical sites with blood collected from subjects on oral anticoagulation therapy and normal subjects not on oral anticoagulation therapy. The INR was measured on fingerstick capillary whole blood on an Alere INRatio®2 PT/INR Monitoring System from each subject and was compared to the INR of a venous plasma sample measured on the Sysmex® CA-560 System using Dade Innovin® reagent (Reference System) collected at the same time from the same subjects. Results of comparison of fingerstick (capillary) whole blood INR results on INRatio®2 System to plasma (venous) INR results on Sysmex®/Dade Innovin® system from all four sites combined are summarized below:

Regression Statistics (Deming):
288 subjects
4 clinical sites
y = 1.05x - 0.05
95% confidence interval of slope: (0.97 to 1.12)
95% confidence interval of intercept: (-0.22 to 0.12)
Pearson correlation coefficient (r) = 0.91

Precision: Precision of the system for professional users was assessed in the clinical trial described above. Professional users tested fingerstick (capillary) whole blood samples. Precision was assessed by conducting duplicate testing of samples from normal and therapeutic subjects (N = number of duplicate pairs) within specified INR ranges. Precision is expressed as a percent coefficient of variation (%CV) and standard deviation (SD) around the Mean INR value for the duplicate pairs within the indicated INR ranges.

Health Care Professionals Precision

User	INR Interval	N	Mean INR	SD	%CV
Professional Capillary (fingerstick)	INR < 2.0 (normal subjects)	22	1.08	0.088	8.16
	INR 2.0 to 4.5	181	2.93	0.180	6.16

Home Use/Patient Self Test (PST)
Accuracy: A multi-center study (4 external clinical sites) was conducted in which subjects on anticoagulant therapy were trained using the user guide and test strip package insert to conduct fingerstick INR testing with the INRatio®2 PT/INR Monitoring System. Subjects tested weekly, over 8 weeks, and the following data were collected at the end of the 8-week period. Fingerstick (capillary) INR results obtained by the trained PST user were compared to corresponding plasma (venous) INR results obtained at a central laboratory (Sysmex CA-560 System using Dade

Innovin® (Reference System)). Results of comparison of fingerstick (capillary) whole blood INR results on INRatio®2 to plasma (venous) INR results on Sysmex®/Dade Innovin® from all four sites combined are summarized below:

Regression Statistics (Deming):
105 subjects
4 clinical sites
y = 1.07x - 0.19
95% confidence interval of slope: (0.92, 1.23),
95% confidence interval of intercept: (-0.55, 0.18)
Pearson correlation coefficient (r) = 0.93

Precision: Precision of the system for PST was assessed in the clinical trials described above. Home PST users tested fingerstick (capillary) whole blood. Precision was assessed by conducting duplicate testing of samples (N = number of duplicate pairs) within specified INR ranges. Precision is expressed as a percent coefficient of variation (%CV) and standard deviation (SD) around the Mean INR value for the duplicate pairs within the indicated INR ranges.

Home Use/Patient Self Test Precision

User	INR Interval	N	Mean INR	SD	%CV
Patient Self Tester (fingerstick)	INR 2.0 to 4.5	66	2.70	0.153	5.68

4. Clinical cut-off**:**
   Not applicable

5. Expected values/Reference range:
   A normal range study was conducted on 120 subjects not on anticoagulant therapy. Testing was conducted with fresh capillary whole blood using 3 lots of INRatio®2 PT/INR Test Strips on both INRatio® and INRatio ®2 monitors. The normal reference range at 95% confidence level was determined to be 0.8-1.3 INR.

N. Instrument Name:
INRatio®2 PT/INR monitor

O. System Descriptions:

1. Modes of Operation:
   Manual mode
2. Software:
   The INRatio®2 Monitor software consists of three modules (Application Operating System (AOS), Application Control Program (ACP), and Prothrombin Time Finding Algorithm modules (PTFA)) that are linked together to form a single program that resides on the micro-controller unit ROM. The AOS controls the hardware functions of the monitor, the ACP controls the user interface, and the PTFA controls the clotting time measurement functions.

   The INRatio®2 PT/INR monitor uses an icon-based, language-independent user interface

that makes the monitor simpler to use, and minimizes labeling and translation requirements.

The monitor software calculates the INR of the sample from the PT using calibration coefficients determined from the strip code.

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
Yes ___X___ or No _____

3. Specimen Identification:
   Manual input.
4. Specimen Sampling and Handling:
   After the test strip is inserted into the monitor, fresh capillary whole blood (obtained by fingerstick) is manually applied directly to the sample well of the test strip.
5. Calibration:
   INRatio®2 PT/INR test strip: Fresh human blood samples from both therapeutic patients and normal subjects are used for test strip calibration. The Test Strips are calibrated to a laboratory reference method (Sysmex CA 560 Coagulation Analyzer). A calibration coefficient for each lot of test strips is calculated. The calibration method is in alignment with WHO Expert Committee on Biological Standardization. 48th Report. World Health Organ Tech Rep Ser. 1999, 889:64-83. The human recombinant thromboplastin is traceable to WHO reference thromboplastin material.

   INRatio®2 Monitor: Factory calibration. The monitor performs self-checks at start-up and throughout the testing process.
6. Quality Control:
   The INRatio®2 PT/INR Test Strip contains two levels of integrated "on-board" quality control (QC) so that external quality control is not required to monitor the performance of the test system. On-board QC is performed with each test. These report one result in the normal range and one result in the therapeutic range. QC ensures that the test is being performed correctly and that the monitor and test strips are working properly together as a system. Before the patient's test results are displayed, the monitor determines whether the control results are within specified limits. If the control results are in range (verifying strip integrity), the monitor reports the patient's test results. If either or both of the controls are out of range, the monitor displays a flashing CAUTION symbol and the applicable QC error message. No test result is given if a QC error is displayed.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In the "Performance Characteristics" Section above:

A study was conducted to verify the acceptable hematocrit range of the INRatio®2 PT/INR Test Strips in conjunction with the INRatio®2 PT/INR monitor. Testing was conducted on the chilled-venous whole blood sample type due to necessity for sample manipulation to targeted hematocrit levels. Sample blood from fifteen (15) subjects on warfarin/VKA therapy (T, INR 2.0 to 4.5) and one normal subject was collected by venipuncture into plain plastic tubes without anticoagulant. Aliquots were made to plain plastic tubes without anticoagulant and samples were immediately placed on ice for up to 90 min for storage. Just prior to testing the blood samples were warmed to 37ºC and then applied to test strips. Samples were contrived to target concentrations. Low hematocrit blood samples were

contrived by dilution of the sample with plasma from the same subject. High hematocrit samples were contrived by concentration of the sample by removal of plasma from the sample. Test results on the INRatio®/INRatio®2 PT/INR system were compared to reference results on the Sysmex CA-560 from citrated venous blood processed to plasma. The results of the study meet all acceptability criteria defined in the clinical protocols and support the acceptable hematocrit range of 25 to 53%.

Q. Proposed Labeling:

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

R. Conclusion:

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