510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K151964

B. Purpose for Submission:

New device

C. Measurand:

International Normalized Ratio (INR) based on Prothrombin Time (PT) response

D. Type of Test:

Electrochemical technology with amperometric detection of thrombin activity

E. Applicant:

Siemens Healthcare Diagnostics, Inc.

F. Proprietary and Established Names:

Xprecia Stride™ Coagulation System and Xprecia™ System PT Controls

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.7750, Prothrombin time test
   21 CFR 864.5425, Multipurpose system for in vitro coagulation studies

2. Classification:

   Class II

3. Product code:

   GJS, Test, time, prothrombin
   GGN, Plasma, coagulation control

4. Panel:

   Hematology (81)

H. Intended Use:

1. Intended use(s):

   The Xprecia Stride™ Coagulation System, which includes the Xprecia Stride™ Coagulation Analyzer and the Xprecia™ System PT/INR Strips, is intended for use by professional healthcare providers to provide an INR (International Normalized Ratio) based on a prothrombin time (PT) response for the monitoring of oral anticoagulation therapy with warfarin, a vitamin K antagonist. The Xprecia Stride™ Coagulation Analyzer is intended to be used with only the Xprecia™ System PT/INR Strips and the Xprecia™ System PT Controls. The analyzer uses fresh capillary (fingerstick) whole blood applied to an Xprecia™ System PT/INR Strip. It is intended for in vitro diagnostic use at the point-of-care.

   Xprecia™ System PT/INR Strips are for use with only the Xprecia Stride™ Coagulation Analyzer for PT/INR determinations by professional healthcare providers. This product is for in vitro diagnostic use.

   Xprecia™ System PT Controls is a combination package containing lyophilized normal and therapeutic plasma controls for use with Xprecia™ Coagulation System for PT/INR determinations by professional healthcare providers. This product is for in vitro diagnostic use.

   The Xprecia Stride™ Coagulation System is intended for use in patients 18 years of age and older. Patients must be stabilized (>6 weeks) on warfarin therapy. The Xprecia Stride™ Coagulation 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):

   For prescription use only

4. Special instrument requirements:

   Xprecia Stride™ Coagulation Analyzer

I. Device Description:

The Xprecia Stride™ Coagulation System is an in vitro diagnostic medical device that is used to provide an INR (International Normalized Ratio) based on a prothrombin time (PT) response in whole blood and is intended for point of care professional use for the monitoring of warfarin (sold under Coumadin® and other brand names) therapy. The Xprecia Stride™ Coagulation System consists of a hand-held analyzer, Xprecia Stride™ Coagulation

Analyzer, used in combination with single-use PT/INR test strips, Xprecia™ System PT/INR Strips, and Liquid Quality Controls (LQC), Xprecia™ System PT Controls.

The Xprecia™ System PT/INR Strip contains the Dade® Innovin® reagent which is a preparation of purified recombinant human tissue factor combined with synthetic phospholipids, calcium chloride, and stabilizers. When a blood sample is applied to the test strip target area, the blood mixes with reagents and activates the coagulation cascade. The clot time is determined by an algorithm and the result is displayed as INR.

The Xprecia™ System PT Controls kit contains assayed Liquid Quality Controls for the assessment of precision and analytical bias in the normal (PT Control 1) and therapeutic (PT Control 2) ranges for the prothrombin time (PT) to be used with the Xprecia™ System PT/INR Strips and Xprecia Stride™ Coagulation Analyzer. The controls consist of lyophilized human plasma, buffers and stabilizers. A calcium chloride diluent present in the kit is used to reconstitute the lyophilized control to activate the clotting process.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   CoaguChek® XS System

2. Predicate 510(k) number(s):

   K060978

3. Comparison with predicate:

Similarities		
Item	New Device Xprecia Stride™ Coagulation System	Predicate CoaguChek® XS System
Intended Use/Indications for Use	The Xprecia Stride™ Coagulation System, which includes the Xprecia Stride™ Coagulation Analyzer and the Xprecia™ System PT/INR Strips, is intended for use by professional healthcare providers to provide an INR (International Normalized Ratio) based on a prothrombin time (PT) response for the monitoring of oral anticoagulation therapy with warfarin, a vitamin K antagonist. The Xprecia Stride™ Coagulation Analyzer is intended to be used with only the Xprecia™ System PT/INR Strips and the Xprecia™ System PT Controls. The analyzer uses fresh capillary (fingerstick) whole blood applied to an Xprecia™ System PT/INR Strip. It is intended for in vitro diagnostic use at the point-of-care. Xprecia™ System PT/INR Strips are for use	The CoaguChek® XS System is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The CoaguChek® XS System uses fresh capillary or non-anticoagulated venous whole blood.

Similarities		
Item	New Device Xprecia Stride™ Coagulation System	Predicate CoaguChek® XS System
	with only the Xprecia Stride™ Coagulation Analyzer for PT/INR determinations by professional healthcare providers. This product is for in vitro diagnostic use. Xprecia™ System PT Controls is a combination package containing lyophilized normal and therapeutic plasma controls for use with Xprecia™ Coagulation System for PT/INR determinations by professional healthcare providers. This product is for in vitro diagnostic use. The Xprecia Stride™ Coagulation Analyzer is intended for use in patients 18 years of age and older. Patients must be stabilized (>6 weeks) on warfarin therapy. The Xprecia Stride™ Coagulation System is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.	
Sample Type	Capillary whole blood	Capillary whole blood and anticoagulated venous whole blood
Operating Principle/Technology	Electrochemical technology with amperometric (electric current) detection of thrombin activity	Same
Test Strip Reagent	Human recombinant thromboplastin	Same
Low Molecular Weight Heparin	Test is insensitive to low molecular weight heparin (LMWH) up to 2 IU anti-factor Xa activity/mL	Same*
Electronic On-board Quality Control	Bi-level on-board quality control checks to verify test strip integrity	Same
Strip Calibration	Each lot of test strips is calibrated to a reference lot traceable to the WHO International Reference Preparation	Same
Reference Range	INR: 0.9 to 1.1	Same

Differences		
Item	Device Xprecia Stride™ Coagulation System	Predicate CoaguChek® XS System
Test Strip Use Time	Within 5 minutes of removing from vial	Within 10 minutes of removing from vial
External Liquid Quality Control	Liquid quality control in the normal and therapeutic range	No external liquid quality control**

Differences		
Item	Device Xprecia Stride™ Coagulation System	Predicate CoaguChek® XS System
Minimum Sample Volume	6 µL	≥8 µL*
Memory	640 patient results 300 LQC results 300 system messages	300 test results**
Heparin	Warfarin patient test results are unaffected by heparin concentrations up to 3U/mL	Warfarin patient test results are unaffected by heparin concentrations up to 0.8U/mL
Test Strip Stability	24 months	21 months
Operating Temperature	15 – 35ºC (59 – 95°F)	15 – 32ºC (59 – 90°F)
Hematocrit Range	Hematocrit range between 22 – 53% do not significantly affect test results	Hematocrit range between 25 – 55% do not significantly affect test results
Measuring Range	0.8 to 4.5 INR	0.8 to 8.0 INR
Built-in barcode reader	Enables automatic entry of strip calibration, lot number and expiration date by reading the 2D barcode on the test strip vial	None

* Per the CoaguChek PT Test Instructions for Use
**Per the CoaguChek XS System User Manual

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

CLSI EP05-A2 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.

CLSI EP05-A3 – Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition.

CLSI EP09-A3 Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition.

CLSI EP07-A2 Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition.

CLSI EP14-A3 Evaluation of Commutability of Processed Samples; Approved Guideline - Third Edition.

L. Test Principle:

The Xprecia Stride™ Coagulation System is a handheld in vitro diagnostic medical device

that uses electrochemical technology to measure the prothrombin time from a fresh capillary (fingerstick) whole blood sample. The fresh capillary (fingerstick) whole blood sample is applied to the Xprecia™ System PT/INR test strips for testing. The Xprecia™ System PT/INR Strip is inserted into the analyzer which applies a small voltage across the electrodes and measures any resulting electrical current as a function of time. A sample chamber in the test strip is filled with the blood sample by capillary action. The test strip contains Dade® Innovin® which is a preparation of purified recombinant human tissue thromboplastin, combined with synthetic phospholipids, calcium, stabilizers, and an electroactive thrombin substrate. An electroactive group released from the thrombin substrate is detected electrochemically at the electrodes in the test strip; the current produced is analyzed by an algorithm to determine the coagulation time. The analyzer displays the International Normalized Ratio (INR) on the screen.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Whole blood precision (Repeatability) across the measuring range was determined for fingerstick (capillary) samples by analyzing them in duplicate. Repeatability was evaluated across four (4) intended use sites using three (3) lots of Xprecia™ System PT/INR test strips per site. The study was executed by a total of 14 operators (minimum of three (3) at each site). The repeatability results passed acceptance criteria. The table below shows the repeatability test results for combined sites:

Summary of Repeatability SDs and %CVs for Xprecia Stride INR results

Site/INR Range (BCS XP)	< 2.0			2.0 to 3.0			3.1 to 4.5		
	Xprecia Stride Within-Run			Xprecia Stride Within-Run			Xprecia Stride Within-Run		
	N	SD	%CV	N	SD	%CV	N	SD	%CV
Site 1	42	0.04	4.0	100*	0.16*	6.0*	34	0.15	4.3
Site 2	42	0.03	3.1	112	0.15	5.7	30	0.15	4.6
Site 3	42	0.05	4.9	96	0.12	4.4	28	0.16	5.0
Site 4	42*	0.09*	9.0*	110	0.12	5.0	28	0.13	4.2
Combined Sites	168	0.06	5.8	418	0.14	5.3	120	0.15	4.5

*Data includes an outlier

Reproducibility was determined by analyzing three (3) lots of Xprecia™ System PT Controls (PT Control 1 and PT Control 2) for 20 operational days, with two runs a day and two replicates per run for each control across four (4) intended use sites and using three (3) lots of Xprecia™ System PT/INR test strips. The study was executed by a total of 12 operators (3 at each site). The reproducibility results passed acceptance criteria. Results are shown in the table below:

Stride Reproducibility by Site

				Within Run		Between Day		Between Run		Between Operator		Total	
Control Level	Site	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
PT Control 1	1	80	1.27	0.03	2.5	0.02	1.2	0.04	2.8	0.00	0.0	0.05	3.9
PT Control 1	2	80	1.29	0.03	2.3	0.00	0.3	0.02	1.5	0.00	0.0	0.04	2.8
PT Control 1	3	80	1.20	0.02	1.8	0.00	0.0	0.00	0.0	0.00	0.3	0.02	1.9
PT Control 1	4	80	1.24	0.04	3.3	0.03	2.3	0.03	2.1	0.03	2.2	0.06	5.0
PT Control 2	1	80	3.18	0.06	1.8	0.00	0.0	0.14	4.4	0.02	0.6	0.15	4.7
PT Control 2	2	80	3.22	0.07	2.2	0.03	1.1	0.06	1.9	0.00	0.0	0.10	3.1
PT Control 2	3	80	3.18	0.05	1.6	0.03	1.0	0.06	1.8	0.03	0.8	0.09	2.7
PT Control 2	4	80	3.11	0.11	3.6	0.14	4.3	0.11	3.7	0.15	4.8	0.26	8.3

Stride Reproducibility Combined Sites

All Sites Combined			Within Run		Between Day		Between Run		Between Operator		Between Site/Analyzer		Total	
Control Level	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
PT Control 1	320	1.25	0.03	2.5	0.01	0.9	0.03	2.1	0.01	0.4	0.04	2.9	0.06	4.6
PT Control 2	320	3.17	0.08	2.4	0.07	2.1	0.10	3.2	0.06	2.0	0.03	1.0	0.16	5.0

b. Linearity/assay reportable range:

A linearity study is not applicable to the Xprecia Stride™ Coagulation System. The INR for the Xprecia Stride™ Coagulation System is calculated mathematically using a standardized thromboplastin based on logs of clot times in seconds.

The assay reportable range (0.8 – 4.5 INR) of the Xprecia Stride™ Coagulation System was established through method comparison studies against both the predicate (Roche CoaguChek® XS System) and the reference device (Siemens BCS XP laboratory analyzer using Dade Innovin recombinant human tissue thromboplastin reagent).

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

Traceability

Each lot of Xprecia™ System PT/INR test strips is factory calibrated to a reference lot of human recombinant thromboplastin traceable to the World Health Organization International Reference Preparation.

Xprecia™ System PT/INR Strips Stability

Closed vial stability

The closed vial stability of 24 months shelf life was established at 5–30°C and up to 75% Relative Humidity (RH); by testing three (3) lots of the Xprecia™ System PT/INR Strips. Testing for closed vial stability was performed at 2, 4, 9, 13, 17, 22, 26, 39, 53, 66, 79, 92, and 105 weeks after time zero (T0). The strips were incubated at three (3) storage conditions (5, 25, and 30°C). Results are consistent with the Xprecia™ System PT/INR Strips claim.

Open vial stability

The open vial stability of 2 months when stored between 5–30°C at up to 75 % RH was substantiated by testing three (3) the Xprecia™ System PT/INR Strip lots over 69 days to verify the effect of the operator opening the strip vial multiple times to remove and use the test strip under controlled temperature and relative humidity conditions. Testing for open vial stability was performed at 5°C/ambient RH, 25°C at 60% RH and 30°C at 75% RH and opened 25 times over the duration of the study to simulate in-use conditions. Results are consistent with the Xprecia™ System PT/INR Strips claim.

Out of vial stability

The 5 minutes out of vial stability claim was established by using three (3) Xprecia™ System PT/INR Strip lots that were exposed to high temperature and humidity conditions for various times up to 12.5 minutes. Single measurements of each test strip were subsequently obtained at 0, 2.5 minutes, 5 minutes, 7.5 minutes, 10 minutes, and 12.5 minutes at a range of conditions 32.7 to 32.9°C and 83 to 89 % RH. Results are consistent with the Xprecia™ System PT/INR Strips claim.

Transport stability

Transport stability was established by evaluating three (3) Xprecia™ System PT/INR Strip lots tested under the following sequence of simulated transport conditions at 0, 12, 18 and 24 months after manufacturing:

a. Test strips stored for 12 hours at 25°C
b. Test strips stored for 74 hours at 30°C, for 46 hours at 35°C, and for 22 hours at 40°C.
c. Test strips stored for 7 hours at 45°C, for 3 hours at 50°C, 3 hours at 55°C. 1 hour at 60°C, and for 1 hour at 65°C.
d. 3 x 1 day Freeze/Thaw (F/T) cycles: Product frozen at -20°C, thawed for 1 day at 2-8°C, and frozen again at -20°C, repeated three times.

All acceptance criteria for the transportation stability were met.

Xprecia™ System PT Controls

Stability

A stability study was conducted for the Xprecia™ System PT Controls using three (3) lots each of Xprecia™ System PT Control 1, PT Control 2 and the calcium chloride ($CaCl_2$) reconstitution buffer. The shelf life for PT Control 1, PT Control 2 and the reconstitution buffer was established as 12 months from the date of manufacture. The stability of the reconstituted control solution was established as 60 minutes when stored at 2–8°C, and 25 minutes when stored at 15–25°C. Results are consistent with the Xprecia™ System PT Controls claim.

Value Assignment

Value assignment was performed by using three (3) vials of PT Controls (PT Control 1 and PT Control 2) from the same lot with three (3) Xprecia™ System PT/INR test strip lots on three (3) Xprecia Stride™ Coagulation Analyzers, in two single determinations. This resulted in 18 results for each control level (3 vials x 2 determinations x 3 analyzers/ strip lot combinations).

The mean of the 18 determinations are to be considered as the assigned value for the PT Control.

d. Detection limit:

Factor sensitivity was assessed for coagulation factors II, V, VII, and X. The factor sensitivity was determined using the nine (9) Xprecia Stride™ Coagulation Analyzers, three (3) lots of Xprecia™ System PT/INR test strips, and normal human red blood cells mixed with various concentrations of normal human plasma and the applicable factor deficient plasma. Each level of factor sensitivity was carried out twice on each analyzer. The study verifies factor sensitivity for the Xprecia™ System PT/INR test strips at the following levels (% of normal factor level; in vitro testing): Factor II <36%; Factor V <58%; Factor VII <52%; and Factor X <68%.

e. Analytical specificity:

Interference Limits

Interference studies were performed for the following interferents: ascorbic acid, acetaminophen, unconjugated bilirubin, conjugated bilirubin, hemolysis, heparin, low molecular weight heparin, triglycerides and uric acid. In addition, an interference study was conducted to characterize the levels of other pharmaceuticals: oritavancin, clopidogrel, fondaparinux, and daptomycin. Interference limits were established using three (3) lots of Xprecia™ System PT/INR Strips tested on eight (8) analyzers each using fresh citrated venous whole blood from both normal and warfarin blood samples spiked separately with the interferents. The acceptance criteria for interference effect of the aforementioned interferents were met. The interference study results show that the following interferents do not interfere with test results up to the concentrations shown:

Interferent	Concentration
Ascorbic Acid	up to 1.5 mg/dL
Acetaminophen	up to 20 mg/dL
Unconjugated Bilirubin	up to 20 mg/dL
Conjugated Bilirubin	up to 29 mg/dL
Hemoglobin	up to 200 mg/dL
Heparin	up to 3 U/mL
Low Molecular Weight Heparin	2 IU anti-factor Xa activity/mL
Triglycerides	3270 mg/dL
Uric Acid	up to 24 mg/dL
Oritavancin	up to 5 mg/L
Clopidogrel	up to 40 mg/L
Fondaparinux	up to 2.5 mg/L
Daptomycin	up to 300 mg/L

Hematocrit

The hematocrit range was evaluated for the Xprecia Stride™ Coagulation Analyzer using capillary samples from 282 patients across four intended use sites. Capillary samples for INR determinations using the Xprecia Stride™ Coagulation System, citrated plasma samples for the central laboratory INR using the Siemens BCS XP , and the measured EDTA venous whole blood hematocrit for each test subject were used in the analysis. The %bias of the Xprecia Stride™ Coagulation System INR to the BCS XP INR was calculated for each test subject and plotted against the hematocrit for that test subject. Data analysis demonstrated that hematocrit range between 22 – 52% does not significantly affect test results.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Accuracy was evaluated by comparing the Xprecia Stride™ Coagulation System against the predicate device, Roche CoaguChek® XS System. The method comparison study was performed on 365 test subjects which included capillary whole blood samples from subjects not receiving warfarin or any other anticoagulant (INR <2.0) and from subjects currently on warfarin therapy (INR 2.0 to 4.5). The method comparison study was conducted across four (4) intended use sites using three (3) lots of Xprecia™ System PT/INR test strips per site with a minimum of three (3) operators per site. The following table summarizes the study results by individual sites and combined sites:

Stride INR vs CoaguChek INR

Statistic	Site 1	Site 2	Site 3	Site 4	All Sites
Slope (95% CI)	1.00 (0.93 – 1.05)	0.94 (0.90 – 1.00)	0.89 (0.82 – 1.00)	0.89 (0.84 – 0.93)	0.93 (0.91 – 1.00)
Intercept (95% CI)	0.0 (-0.1 – 0.1)	0.0 (-0.1 – 0.1)	0.0 (-0.1 – 0.2)	0.1 (0 – 0.2)	0.0 (-0.1 – 0.1)
Coefficient of determination (r^2)	0.94	0.94	0.94	0.93	0.93
Total Samples	90	96	89	90	365

The results support the claim that the Xprecia Stride™ Coagulation System candidate device and the Roche CoaguChek® XS System predicate device are substantially equivalent.

Method Comparison with Reference device:

Accuracy was also evaluated by comparing the INR results of capillary samples measured on the Xprecia Stride™ Coagulation System against the INR of venous plasma samples measured on Siemens BCS XP laboratory analyzer using Dade® Innovin® recombinant human tissue thromboplastin reagent (reference device). The method comparison study was performed on 364 subjects across four (4) sites using three (3) lots of Xprecia™ System PT/INR test strips at each site, and a minimum of three (3) operators per site. Results of INR values measured on Xprecia Stride™ Coagulation System using fingerstick capillary whole blood samples were compared to the INR measured on BCS XP using venous plasma samples. The data from individual sites were combined and a Passing-Bablok regression analysis was performed. The results support the claim that the Xprecia Stride™ Coagulation System candidate device and the BCS XP reference device are substantially equivalent. The following table summarizes the study results by individual sites and combined sites:

Stride INR vs BCS XP INR

Statistic	Site 1	Site 2	Site 3	Site 4	All Sites
Slope (95% CI)	1.08 (1.00 – 1.17)	1.00 (0.95 – 1.06)	0.92 (0.84 – 1.00)	0.93 (0.86 – 1.00)	1.00 (0.95 – 1.00)
Intercept (95% CI)	0.0 (-0.2 – 0.1)	0.1 (0 – 0.1)	0.1 (0 – 0.2)	0.1 (0 – 0.2)	0.0 (0 – 0.1)
Coefficient of determination (r^2)	0.89	0.90	0.91	0.91	0.89
Total Samples	90	96	87	91	364

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):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

A normal range study was conducted on 120 healthy subjects not on anticoagulation therapy. Testing performed on the warfarin-free individuals using capillary samples demonstrated that the normal reference range at 95% of the INRs ranged between 0.9 – 1.1 INR.

N. Instrument Name:

Xprecia Stride™ Coagulation Analyzer

O. System Descriptions:

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes ____x____ or No _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes _____ or No ___x_____

2. Software:

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

Yes ___x_____ or No _____

3. Specimen Identification:

   A built-in barcode reader scans the barcode label associated with a patient sample.

4. Specimen Sampling and Handling:

   The Xprecia™ System PT/INR Strips are intended for single-use only. Once the test strip is inserted into the analyzer, a drop of fresh capillary whole blood sample collected by fingerstick is manually applied to the test strip target area and analyzed.

5. Calibration:

   Xprecia™ System PT/INR strips:
   Each lot of Xprecia™ System PT/INR test strips is factory calibrated to a reference lot of human recombinant thromboplastin traceable to the World Health Organization International Reference Preparation. An International Sensitivity Index (ISI) and Mean Normal Prothrombin Time (MNPT) values are assigned by calibration for each lot and embedded on the barcode label on the test strip vial along with the lot number and expiration date. Metrological traceability was achieved by following WHO Technical Report Series 889 Annex 3 - Guidelines for Thromboplastins and Plasmas Used to Control Oral Anticoagulant Therapy.

   Xprecia Stride™ Coagulation Analyzer:
   When the analyzer is first turned on, the instrument performs a series of electronics, signal, software and memory integrity checks, as well as ensuring there is sufficient battery voltage to operate the Xprecia Stride™ Analyzer. The key tests during this phase are the Heater/Thermistor check along with the Strip Port Hardware check. These are part of the overall Electronics Integrity Check. Failure to pass any of these power-on tests will prevent further operation of the analyzer.

6. Quality Control:

   The Xprecia Stride™ Coagulation System consists of two levels of electronic onboard quality controls. When a test strip is inserted, the Xprecia Stride ™ Coagulation Analyzer automatically conducts two on-strip quality control checks designed to help ensure test strip integrity. The first control checks the presence of adequate sample reagent on the test strip, and the second control detects test strip degradation due to exposure to environmental conditions.

   The Xprecia Stride™ Coagulation Analyzer also uses Liquid Quality Controls (LQCs). The Xprecia™ System PT Controls kit contains assayed controls for the assessment of precision and accuracy in the normal (PT Control 1) and therapeutic (PT Control 2) range for the prothrombin time (PT) to be used with Xprecia™ System PT/INR Strips. The PT Control 1 and PT Control 2 are run and evaluated the same way as patient samples. The assigned values and ranges for each lot of PT Control 1 and PT Control 2 appear on each control vial as a barcode to be read by the Xprecia Stride™ Coagulation Analyzer.

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

Cleaning Robustness Testing

To perform the Stride ™ Coagulation Analyzer cleaning step, the operator should use a Sani-Cloth® Plus to wipe all surface areas of the analyzer to remove all blood and other body fluids. During the Stride ™ Coagulation Analyzer disinfection step, the operator uses a Sani-Cloth® Plus to thoroughly wet all surface areas of the analyzer. The operator also carefully disinfects the front and grooved back of the test strip port protective cap with the Sani-Cloth® Plus. After 2 minutes exposure time (allow the analyzer to remain wet for 2 minutes), then let air dry. The Stride ™ Coagulation Analyzer lifespan claim is 7,300 cleaning cycles which is equivalent to 2 years of analyzer life.

One (1) cycle = One (1) wipe for cleaning + One (1) wipe for disinfecting
10 cleaning cycles per day x 365 days x 2 years = 7,300 cleaning cycles.

The lifespan of the analyzer will vary depending on actual usage.

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.