DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 30, 2016

Siemens Healthcare Diagnostics
Noor Malki
Vice President, Quality Management
2 Edgewater Drive
Norwood, MA 02062

Re: K151964
Trade/Device Name: Xprecia Stride™ Coagulation System
Xprecia™ System PT Controls
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin time test
Regulatory Class: Class II
Product Code: GJS, GGN
Dated: September 26, 2016
Received: September 27, 2016

Dear Ms. Malki:

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 (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. 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.

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 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151964

Device Name
Xprecia Stride™ Coagulation System
Xprecia™ System PT Controls

Indications for Use *(Describe)*
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 Systemis 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.

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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510(k) Summary

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

1.0 Submitter Information

Owner	Siemens Healthcare Diagnostics, Inc. 2 Edgewater Drive Norwood, MA 02062
Contact	Noor Malki VP Clinical, Medical, Regulatory & Quality Operations Siemens Healthcare Diagnostics Point of Care (POC) Business noor.malki@siemens.com TEL 781-269-3401
Date Summary Prepared	September 30, 2016

2.0 Device Information

Proprietary Name	Xprecia Stride™ Coagulation System Xprecia™ System PT Controls
Common Name	Prothrombin time test
Panel	Hematology

Regulatory Information:

Classification				
Device	**Regulation Section**	**Device Class**	**Product Code**	**Test**
Xprecia Stride™ Coagulation System	21 CFR 864.7750	II	GJS	Prothrombin time test
Xprecia™ System PT Controls	21 CFR 864.5425	II	GGN	Plasma, coagulation control

3.0 Substantial Equivalence Information

Element	Predicate device
Predicate Device Name	CoaguChek® XS System
Common Name	Prothrombin time test
510(k) Number	K060978
Manufacturer	Roche Diagnostics

4.0 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 International Normalized Ratio (INR) 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.

5.0 Indications for Use / Intended 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 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.

6.0 Summary Comparison of Technological Characteristics (Predicate)

Similarities		
Item	**Xprecia Stride™ Coagulation System (New device)**	**CoaguChek® XS System (Predicate)**
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	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.

6.0 Summary Comparison of Technological Characteristics (Predicate)

Similarities		
Item	**Xprecia Stride™ Coagulation System (New device)**	**CoaguChek® XS System (Predicate)**
	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.	
Sample Type	Capillary whole blood	Same and non-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	Same

6.0 Summary Comparison of Technological Characteristics (Predicate)

Similarities		
Item	**Xprecia Stride™ Coagulation System (New device)**	**CoaguChek® XS System (Predicate)**
	to a reference lot traceable to the WHO International Reference Preparation	
Reference Range	INR: 0.9 to 1.1	Same

Differences		
Item	**Xprecia Stride™ Coagulation System (New device)**	**CoaguChek® XS System (Predicate)**
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**
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 – 52% 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

7.0 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 Process Samples; Approved Guideline - Third Edition

8.0 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.

9.0 Performance Characteristics

1. <u>Analytical Performance</u>

a) <u>Precision / Repeatability</u>:

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 PT/INR test strips per site. The study was executed by a total of fourteen (14) operators (minimum of three (3) at each site). The table below shows the repeatability results for combined sites. The acceptance criterion of ≤10% CV across the measuring range was met.

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 / Intermediate Precision:

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 2 runs a day and 2 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 twelve (12) operators (three (3) at each site).

Xprecia 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

Xprecia 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 (WHO Technical Report Series 889 Annex 3 - Guidelines for thromboplastins and plasmas used to control oral anticoagulant therapy).

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). Dade® Innovin® Reagent was used on the BCS XP for prothrombin time (PT) determinations. Data collected across the assay reportable range from the method comparison studies were used to demonstrate linearity on the Xprecia Stride™ Coagulation Analyzer.

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

Closed Vial Stability

The closed vial stability of 24 months shelf life was established as 5-30°C up to 75% Relative Humidity (RH); by testing three (3) lots of 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 T0. The strips were incubated at three (3) storage conditions (5, 25, and 30°C).

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) 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.

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 twelve and a half 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 overall of 32.7 to 32.9°C and 83 to 89 % RH.

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:

- 25°C for 12 hours, 30°C for 74 hours, 35°C for 46 hours, 40°C for 22 hours, 45°C for 7 hours, 50°C for 3 hours, 55°C for 3 hours, 60°C for 1 hour, 65°C for 1 hour
- 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

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 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.

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 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:

The 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.

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

The hematocrit range was evaluated for the Xprecia Stride™ Coagulation Analyzer using capillary samples from 282 patients across four (4) intended use sites. Capillary samples for INR determinations using the Xprecia Stride™ Coagulation System, citrated plasma samples for the central laboratory (Siemens BCS XP) INR, 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% do not significantly affect test results.

f) Assay cut-off:

Not applicable.

2. <u>Comparison studies</u>

a. <u>Method Comparison with Predicate device</u>

Accuracy was evaluated by comparing the Xprecia Stride™ Coagulation System against the predicate device, Roche CoaguChek® XS System. The clinical 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 – 0.2)	0.0 (-0.1 – 0.1)
Coefficient of determination (r2)	0.94	0.94	0.94	0.93	0.93
Total Samples	90	96	89	90	365

Method Comparison with Lab 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 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 (r2)	0.89	0.90	0.91	0.91	0.89
Total Samples	90	96	87	91	364

b. Matrix Comparison

Not applicable. The Xprecia Stride™ Coagulation System is intended for capillary whole blood samples only.

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 95% of the INRs ranged between 0.9 - 1.1.

10.0 Instrument Name:

Xprecia Stride™ Coagulation Analyzer

11.0 System Description

1. Modes of Operation

Manual, closed system. Xprecia™ System PT/INR Strips are designed for use only with the Xprecia Stride™ Coagulation Analyzer; other test strips will not work with the analyzer.

2. Software

The user operates the Xprecia Stride™ Coagulation Analyzer through a touch screen with a user interface that consists primarily of icons (symbols). The user interacts with the touch screen display to select tasks to perform and to enter alphanumeric characters on certain screens. Some information such as an Operator ID or a Patient ID may also be entered using the bar code reader at the bottom of the analyzer. The touch screen displays messages, options, and requests for information. The Home screen contains menu icons from which the operator can select to set up the system, perform a patient test, recall previous results, and perform quality control tests. The system records error and warning messages in the Event log which is accessed through the Recall function.

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 Strip is 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™ Coagulation Analyzer. The key tests during this phase are the Heater/ Thermistor check along with the Strip Port Hardware check. These are part of 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 Analyzer 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 check verifies the presence of adequate sample reagent on the test strip, and the second check assesses the test strip for 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 International Normalized Ratio (INR) to be used with Xprecia™ System PT/INR Strips. The PT Control 1 and PT Control 2 are run and evaluated in 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.

12.0 Conclusion

The results of these studies demonstrate that the Xprecia Stride™ Coagulation System is similar to the predicate in both Technological Characteristics and Intended Use. The data presented are a summary of external clinical evaluation, internal laboratory evaluation, and software development information. The Xprecia Stride™ Coagulation System performance was shown to be substantially equivalent to the predicate device and demonstrated a strong correlation to the reference method.