510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I   Background Information:

A   510(k) Number

K230802

B   Applicant

Universal Biosensors Pty Ltd

C   Proprietary and Established Names

Xprecia Prime Coagulation System

D   Regulatory Information

Product Code(s)		Regulation	
GJS	Class II	21 CFR 864.7750 - Prothrombin Time Test	HE - Hematology

II   Submission/Device Overview:

A   Purpose for Submission:

New device

B   Measurand:

Prothrombin Time (PT) in International Normalized Ratio (INR) and seconds

C   Type of Test:

Electrochemical technology with amperometric detection of thrombin activity

III   Intended Use/Indications for Use:

A   Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:

The Xprecia Prime Coagulation System, which includes the INR Coagulation Analyzer (Meter) and PT/INR Test Strips, is for the determination of International Normalized Ratio (INR) for the monitoring of oral anticoagulation therapy with Warfarin (a vitamin K antagonist) in fresh capillary whole blood from a fingerstick. The results are reported in INR as well as in seconds. It is intended to be used to monitor patients 18 years of age or older who are stable on vitamin K antagonist therapy for at least six weeks and is not intended for use in patients who are transitioning from heparin treatment to vitamin K antagonist therapy. The Xprecia Prime Coagulation System is an in-vitro diagnostic device intended for multi-patient use in professional healthcare settings including CLIA Waived and Point of care settings.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:

Xprecia Prime Coagulation Analyzer

IV Device/System Characteristics:

A Device Description:

The Xprecia Prime Coagulation System is intended to monitor the International Normalized Ratio (INR) of patients undergoing anticoagulation therapy with warfarin (Vitamin K antagonist). It consists of the Xprecia Prime Coagulation Analyzer (meter) and Xprecia Prime PT/INR Strips.

The Xprecia Prime system analyses a blood sample taken from the patient by fingerstick. The sample is transferred from the patient's finger to a test strip that has been inserted in the Xprecia Prime Coagulation Analyzer. The blood is mixed with a reagent contained within the test strip and the analyzer detects when clotting has occurred. The result is then displayed on the analyzer's screen in either units known as INR or in calibrated seconds.

B Principle of Operation:

The Xprecia Prime Coagulation System uses electrochemical technology with amperometric (electric current) detection of thrombin activity to generate clot time. When a blood sample is transferred from the patient's finger to a test strip that has been inserted in the Xprecia Prime Coagulation Analyzer, thromboplastin activates the coagulation cascade which leads to the formation of thrombin. Thrombin cleaves the thrombin substrate creating an electrochemically active peptide, which generates an electrical signal. The signal is converted to an International Normalized Ratio (INR) value and the result is then displayed on the analyzer's screen in either units known as the INR or in calibrated seconds. The Xprecia Prime Coagulation System has been designed with integrated quality control functions in both the meter and the test strips. The meter performs a check of its electronic components and functions every time it is turned on. During each test, the meter looks for specific features in the strip's response that confirm the

presence of the reagents in the strips and indicate if the strip has been unacceptably degraded due to exposure to extreme environmental conditions.

C Instrument Description Information:

1. Instrument Name:
   Xprecia Prime Coagulation Analyzer

2. Specimen Identification:
   Barcode scanner or onscreen keyboard

3. Specimen Sampling and Handling:
   Whole blood samples collected from a fingerstick (capillary). Specimen is applied directly to the test strip after collection.

4. 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 (WHO) International Reference Preparation (IRP). 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.

   Xprecia Prime 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 Prime Coagulation Analyzer. Failure to pass any of these power-on tests will prevent further operation of the analyzer.

5. Quality Control:

   Internal Quality Control
   The Xprecia Prime Coagulation Analyzer has a number of integrated quality-control functions:
   - Component and function check is performed every time the analyzer is turned on.
   - Barcode information on the strip and vial are read by a scanner inside the Xprecia Prime analyzer. The analyzer then checks:
     - the strip's expiration date and lot information, and
     - the strip's integrity.
   - During the test, the strip's integrity is monitored. The strip's temperature is also controlled to ensure test results are reproducible.

   External Quality Controls
   The Xprecia Prime Coagulation System is only to be used with the Xprecia Systems PT Controls (Liquid quality control (LQC) solution Level 1 and 2; K151964). External controls should be performed with every new lot, new shipment, or as required by local, state, and federal or national regulations. New operators should perform LQC prior to starting to

perform patient testing. Use of external QC ensures that the Xprecia Prime Coagulation System is working as designed. Each Xprecia Systems PT Controls kit contains two levels of vials of plasma and diluent. The reconstitution of the LQC requires the user to pipette the diluent solution into the plasma vial and let the solution stand for at least 5 minutes. The INR target of the reconstituted LQC 1 will be around 1.0 INR and LQC 2 will be in the therapeutic range of oral anticoagulant therapy, INR of 2.0–4.5.

-Discuss carry0ver: possible voltage surge from high/low results

V   Substantial Equivalence Information:

A   Predicate Device Name(s):
Coaguchek XS System

B   Predicate 510(k) Number(s):
K060978

C   Comparison with Predicate(s):

Device & Predicate Device(s):	K230802	K060978
Device Trade Name	Xprecia Prime Coagulation System	Coaguchek XS System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Xprecia Prime Coagulation System, which includes the INR Coagulation Analyzer (Meter) and PT/INR Test Strips, is for the determination of International Normalized Ratio (INR) for the monitoring of oral anticoagulation therapy with Warfarin (a vitamin K antagonist) in fresh capillary whole blood from a fingerstick. The results are reported in INR as well as in seconds. It is intended to be used to monitor patients 18 years of age or older who are stable on vitamin K antagonist	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 nonanticoagulated venous whole blood.

	therapy for at least six weeks and is not intended for use in patients who are transitioning from heparin treatment to vitamin K antagonist therapy. The Xprecia Prime Coagulation System is an in-vitro diagnostic device intended for multi-patient use in professional healthcare settings including CLIA Waived and Point of care settings.	
Measuring Range	0.8 – 8.0 INR	Same
Operating Principle/Technology	Electrochemical technology with amperometric (electric current) detection of thrombin activity	Same
Test Strip Reagents	Human recombinant thromboplastin	Same
Test Strip Use Time	10 minutes	Same
Traceability	WHO International Reference Preparation	Same
Calibration Traceability	Each lot of test strips is calibrated to a reference lot traceable to the WHO International Reference Preparation	Same
Operating temperature	15ºC to 32ºC 80% maximum (non-condensing) Relative Humidity	Same
Quality Control	Internal and External	Same
On-Board Quality Control	On-board fully integrated quality controls which use electrochemical signals to detect test strip integrity	Same
Reference Range	INR: 0.9 to 1.1	Same

Hematocrit Range	25–55%	Same
General Device Characteristic Differences		
Specimen Type	Capillary whole blood	Capillary whole blood and non-anticoagulated whole blood
External Liquid Quality Control	Liquid quality control in the normal and therapeutic range	No external liquid quality control
QC Lock-Out	Available through programming	Not Available
Calibration	Lot specific programmed into strip lot barcode	Lot specific code chip selected by end user
Sample Volume	8 µL	10 µL
Memory Capacity	640 patient results 300 LQC results 300 system messages	300 test results with date & time
Test Strip Stability	24 months	21 months
Testing Strip Sample Application	Top side only	Top and side application
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

VI   Standards/Guidance Documents Referenced:

- CLSI EP05-A3 – *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline* – Third Edition
- CLSI EP07-A2 – *Interference Testing in Clinical Chemistry*; Approved Guideline – Third Edition
- CLSI EP09c – *Measurement Procedure Comparison and Bias Estimation Using Patient Samples;* Approved Guideline – Third Edition
- CLSI EP14-A3 – *Evaluation of Commutability of Processed Samples*; Approved Guideline -Third Edition
- CLSI GP41 – *Collection of Diagnostic Venous Blood Specimens*, 7th edition
- CLSI H47-A2 – *One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test*; Approved Guideline - Second Edition.
- CLSI POCT14-ED2 – *Point-of-care Coagulation Testing and Anticoagulation Monitoring,* Second edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Intermediate Precision
A single site intermediate precision study was performed by two trained operators over the course of 20 non-consecutive days with two runs per day and two replicates per run. Each operator used three Xprecia Prime PT/INR strips lots, six Xprecia Prime Coagulation Analyzers, and three levels of quality control material (K151964 – Xprecia System PT Control Level 1 and 2 and K771346 Ci-Trol Coagulation Control III). The 20-day precision of the Xprecia Prime Coagulation System has been demonstrated to be within the acceptance criteria at each control level and for each cartridge lot. The results of this study demonstrated acceptable within-laboratory precision for all three control levels.

Intermediate Precision - INR														
			Repeatability		Between Run		Between Day		Within Lot		Between Lot		Within Lab	
QC	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	240	1.18	0.03	2.2	0.02	1.6	0.00	0.0	0.03	2.7	0.03	2.8	0.05	3.9
2	240	2.81	0.03	1.0	0.01	0.5	0.00	0.0	0.03	1.1	0.01	0.4	0.03	1.2
3	240	6.52	0.07	1.1	0.11	1.6	0.04	0.6	0.13	2.0	0.13	2.0	0.18	2.8

Intermediate Precision - Seconds														
			Repeatability		Between Run		Between Day		Within Lot		Between Lot		Within Lab	
QC	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	240	13.95	0.09	0.6	0.11	0.8	0.00	0.0	0.14	1.0	0.16	1.2	0.22	1.5
2	240	33.76	0.23	0.7	0.22	0.6	0.00	0.0	0.32	0.9	0.23	0.7	0.39	1.2
3	240	78.28	0.79	1.0	1.23	1.6	0.55	0.7	1.56	2.0	1.50	1.9	2.17	2.8

Repeatability
The repeatability data was collected from the method comparison study performed at four CLIA-waived sites. Two capillary samples (two fingersticks) collected from each subject were tested by the same untrained operator using the same meter and the same strip lot, resulting into a total of 399 paired tests (132 normal subjects and 267 warfarin subjects). The study was performed by 11 untrained operators using three Xprecia Prime PT/INR test strip lots and 12 Xprecia Prime Coagulation Analyzers. Data analysis was carried out by site, all sites combined and by clinically relevant ranges. The mean, pooled standard deviation, %CV and their respective 95% confidence intervals (CI) for INR were calculated for each subject level. The table below summarize this data for all sites combined. The results of the study for capillary samples demonstrate the Xprecia Prime Coagulation System repeatability is acceptable.

Capillary Whole Blood Repeatability Summary Prothrombin Time (INR)				
INR	**N**	**Mean**	**SD (95% CI)**	**% CV (95% CI)**
< 1.9	350	1.17	0.05 (0.05, 0.6)	4.2 (4.3, 5.1)
2–3.59	234	2.71	0.14 (0.12, 0.16)	5.2 (4.4, 5.9)
3.6–4.59	116	4.07	0.17 (0.14, 0.21)	4.2 (3.4, 5.2)
4.6–8.0	98	5.87	0.34 (0.28, 0.42)	5.8 (4.6, 7.2)

Capillary Whole Blood Repeatability Summary Prothrombin Time (seconds)				
PT Range	**N**	**Mean**	**SD (95% CI)**	**% CV (95% CI)**
9.6–24.3	360	14.32	0.44 (0.40, 0.49)	3.1 (2.8, 3.4)
24.4–56.8	346	38.73	1.96 (1.77, 2.18)	5.1 (4.6, 5.6)
56.9–96.0	92	71.39	4.14 (3.40, 5.14)	5.8 (4.8, 7.2)

Reproducibility

The reproducibility of the Xprecia Prime Coagulation System was performed at three external CLIA-waived sites. Testing at each site was performed over five non-consecutive days in the hands of two untrained operators at each site (n=6 operators). Each operator tested two levels of quality control materials (K151964 – Xprecia System PT Control Level 1 and 2) twice per day with a minimum of two hours between each run. Each quality control level was tested in triplicate (2 operators x 1 run/operator x 3 replicates x 5 days = 30 observations for each site per QC level). All results passed the established acceptance criteria.

All Sites Combined (INR)														
QC Level	**N**	**Mean**	**Repeatability**		**Between Run**		**Between Day**		**Between Operator**		**Between Site**		**Overall Reproducibility**	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
1	90	1.19	0.02	2.0	0.02	1.3	0.02	1.8	0.04	3.0	0.02	1.8	0.04	3.7
2	90	2.62	0.03	1.3	0.00	0.0	0.00	0.0	0.03	1.3	0.03	1.0	0.04	1.6

All Sites Combined (Seconds)														
QC Level	**N**	**Mean**	**Repeatability**		**Between Run**		**Between Day**		**Between Operator**		**Between Site**		**Overall Reproducibility**	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
1	90	14.26	0.14	1.0	0.24	1.7	0.00	0.0	0.28	1.9	0.37	2.6	0.46	3.2
2	90	31.45	0.23	0.7	0.11	0.3	0.14	0.4	0.29	0.9	0.30	1.0	0.42	1.3

2. Linearity:
   Not applicable.

3. Analytical Specificity/Interference:
   The interference performance of the Xprecia Prime Coagulation System was evaluated in the presence of potentially interfering endogenous or exogenous substances. The effect of each substance at each INR level (normal and therapeutic) was evaluated by comparing the performance of a test sample spiked to a high concentration of the substance and a control sample spiked with an equal volume of solvent. For an identified interferent, a dose-response was performed to determine the degree of interference as a function of the substance concentration. The common exogenous and endogenous interfering substances and their interference results are listed below and showed no significant interference up to the indicated concentration for all samples tested.

Substance	Maximum Test Concentration with no Interference
Acetaminophen	20 mg/L
Amoxicillin	5.4 mg/dL
Atorvastatin	96 mg/dL
Cefitriaxone	84 mg/dL
Clexane	3 IU/mL
Conjugated Bilirubin	40 mg/dL
Dexamethesone	12 mg/L
Ethinyl Estradiol	0.288 mg/L
Fondaparinux Sodium	5 mg/L
Hemoglobin	1000 mg/dL
Heparin	3300 U/L
Ibuprofen	219 mg/L
Lactate Dehydrogenase	250 U/L
Levonorgestrel	1.8 mg/L
Potassium Chloride	5 mmol/L
Prasugrel	72 mg/L
Prednisolone	3 mg/L
Sodium Salicylate	0.0695 g/dL
Testosterone	480 mg/L
Ticagrelor	108 mg/L
Triglycerides	1500 mg/dL
Unconjugated Bilirubin	40 mg/dL
Uric Acid	24 mg/dL

For the identified INR test interferents Apixaban, Calcium Dobesilate, Dabigatran, Daptomycin, Edoxaban, L-Ascorbic Acid, Protamine Sulfate, and Rivaroxaban, a dose-response experiment was performed.

Substance	Maximum Test Concentration with no Interference
Apixaban	0.08 mg/L
Calcium Dobesilate	30 mg/L
Dabigatran	0.005 mg/L
Daptomycin	552 mg/L
Edoxaban	0.06 mg/L
L-Ascorbic Acid	3 mg/dL
Protamine Sulfate	7.5 mg/L
Rivaroxaban	0.06 mg/L

Hematocrit

The hematocrit range was evaluated for the Xprecia Prime Coagulation System using capillary samples from 371 patients across four intended use sites in the Method Comparison study. Capillary samples for INR determinations using the Xprecia Prime Coagulation System, citrated plasma samples for the central laboratory INR using the Sysmex Automated Blood Coagulation Analyzer CS-2500 (K172286), and the measured EDTA venous whole blood hematocrit for each test subject were used in the analysis. Hematocrit was determined using Sysmex XN-11 (K141681), Sysmex XN 9000 (K112605), or Sysmex XS-1000i (K081610) analyzers. Data analysis demonstrated that hematocrit range between 25–55% does not significantly affect test results.

Factor Sensitivity

The factor sensitivity for factors FII, FV, FVII and FX was determined using samples prepared by combining normal plasma, red blood cells, and factor-deficient plasma with various percent (%) factor activity ranging from 0%–100%. Each factor was tested at 11 factor activity levels with three strip lots and eight replicates per lot on 24 Xprecia Prime Coagulation Analyzers. The mean clot time calculated for the normal plasma sample (sample without pooled factor deficient plasma) is the average clot time in 24 Xprecia Prime Coagulation Analyzers (8 analyzers x 3 strip lots). Based on CLSI H47: One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline - Second Edition, factor sensitivity was calculated based on the factor level at which the PT rises above the upper limit of the established reference interval. The sensitivity of the Xprecia Prime Coagulation System has been characterized to Factor II–50%, Factor V–60%, Factor VII–50%, and Factor X–60%.

4. <u>Assay Reportable Range:</u>

The assay reportable range of the Xprecia Prime Coagulation System was established through method comparison studies. The reportable range for INR is 0.8–8.0 and for PT in seconds is 9.6–96.0.

5. <u>Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):</u>

Traceability

The traceability of the prothrombin time test on the Xprecia Prime Coagulation System has been established against a reference lot of human recombinant thromboplastin traceable to the World Health Organization (WHO) International Reference Preparation (IRP). Xprecia System PT/INR test strips lots manufactured by Universal Biosensors have been calibrated

using the rTF/16 (WHO 5th International Standard Thromboplastin, Human, Recombinant, Plain).

Shelf-life Stability for Xprecia Prime PT/INR Strips
A real-time shelf-life stability study was conducted using three lots of Xprecia Prime PT/INR Strip lots at 5ºC with ambient relative humidity (RH) and 30ºC with 75% RH storage conditions. Three levels of quality control material (K151964–Xprecia System PT Control Level 1 and 2 and K771346–Ci-Trol Coagulation Control III), unaltered whole blood samples to reflect normal INR range and warfarin treated samples to reflect therapeutic INR range were tested at time zero and ten different test events: 4.5, 6, 7, 9, 12, 15, 18, 21, 24, and 27 months. The stability results for the Xprecia Prime PT/INR Strip lots support a shelf-life of 24 months at 5ºC–30ºC with < 75% RH.

Open Vial Stability
An open vial stability study was conducted using one lot of Xprecia Prime PT/INR Strips. The vials were opened 25 times over a 3-month period at both 5ºC with ambient relative humidity (40 ± 20 % RH) and 30ºC with 75% RH storage conditions. Three levels of quality control material (K151964–Xprecia System PT Control Level 1 and 2 and K771346–Ci-Trol Coagulation Control III), unaltered whole blood samples to reflect normal INR range and warfarin treated samples to reflect therapeutic INR range were tested at time zero and three different test events: 7, 15, and 24 months. The stability results for the Xprecia Prime PT/INR Strip lots support an open vial storage claim of 20 months at 5ºC–30ºC with < 75% RH.

In-Use/Out of Vial Stability
An in-use stability study was conducted using one lot of Xprecia Prime PT/INR Strip lots at 5ºC with ambient relative humidity (RH) and 30ºC with 75% RH storage conditions. Three levels of quality control material (K151964–Xprecia System PT Control Level 1 and 2 and K771346–Ci-Trol Coagulation Control III), unaltered whole blood samples to reflect normal INR range and warfarin treated samples to reflect therapeutic INR range were tested at time zero and ten different test events: 4.5, 6, 7, 9, 12, 15, 18, 21, 24, and 27 months. Strips were assessed by exposing strips out of the vial for the following times at each test event: 0, 2.5, 5, 7.5, 10, and 12.5 minutes out of the vial. The stability results for the Xprecia Prime PT/INR Strip lots support an in-use or out of vial storage claim of 10 minutes 5ºC–30ºC with < 75% RH for the entire 24 months of the shelf-life.

Transport Stability
All the Xprecia Prime PT/INR Test Strips vials tested for real-time shelf-life, open vial, and in-use studies were subjected to the described shipping simulation prior to placing them into their respective storage conditions (5°C / 30°C) to ensure that the stability studies performed would reflect real world performance of the product. Three lots of strip vials were subjected to Pressure Decay Testing and then placed into an environmental chamber for the shipping simulation. The shipping trial consists of a transport simulation followed by a 3-day freeze/thaw cycle to simulate temperature stress as they are transported. Strips have met all acceptance criteria for closed vial, out of vial, and open vial studies, after being subjected to an AR4 temperature profile followed by three freeze-thaw cycles, to represent worst-case transport conditions. Therefore, the transport simulation requirements have been met and the product is appropriate for ambient shipping/ transport.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Refer to Method Comparison below.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison:

   The method comparison study was performed at four U.S. point-of-care clinical sites with CLIA Waiver certificates. Group 1 consisted of 320 patients on warfarin therapy for at least six weeks prior to enrollment and Group 2 consisted of 130 healthy, normal subjects. The study was conducted with three lots of Xprecia Prime PT/INR strips and 12 Xprecia Prime Coagulation Analyzers by 11 untrained operators. Each patient had two fingerstick samples collected by the untrained operator for testing on the Xprecia Prime Coagulation System and the predicate, Coaguchek XS (K060978). The Xprecia Prime Coagulation System is substantially equivalent to the CoaguChek XS System.

Method Comparison Results for Xprecia Prime Coagulation System vs. Roche Coaguchek						
Analyte	**N**	**Xprecia Range**	**CoaguChek Range**	**Slope (95% CI)**	**Intercept (95% CI)**	**(r)**
INR	401	0.8–7.7	0.9–7.9	0.96 (0.939, 0.985)	-0.01 (-0.083, 0.065)	0.97
PT (seconds)	401	9.7–91.5	10.5–95.3	0.962 (0.940, 0.985)	-1.131 (-0.998, 0.736)	0.97

   In addition, a venipuncture was performed for PT and INR determinations on the laboratory method, Sysmex Automated Blood Coagulation Analyzer CS-2500 (K172286). Capillary results from the Xprecia Prime Coagulation System demonstrates acceptable comparison to venous whole blood collected in 3.2% citrated tubes on the Sysmex Automated Blood Coagulation Analyzer CS-2500.

Method Comparison Results for Xprecia Prime Coagulation System (FS) vs. Sysmex CS-2500 (venous)						
Result	N	Xprecia Range	Sysmex Range	Slope (95% CI)	Intercept (95% CI)	(r)
INR	397	0.8–7.7	0.9–7.2	1.1 (1.073, 1.117)	-0.12 (-0.183, -0.056)	0.98
PT (seconds)	397	9.7–95.5	9.7–72.6	1.307 (1.28, 1.33)	-2.341 (-3.12, -1.56)	0.98

C   Clinical Studies:

1.   <u>Clinical Sensitivity:</u>

Not applicable.

2.   <u>Clinical Specificity:</u>

Not applicable.

3.   <u>Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):</u>

Not applicable.

D   Clinical Cut-Off:

Not applicable.

E   Expected Values/Reference Range:
Normal range testing was conducted on 120 healthy subjects who were not on oral anticoagulant therapy from the Method Comparison study. Samples were tested on three lots of Xprecia Prime PT/INR strips. Results demonstrated a normal range of 0.9 to 1.1 INR with more than 95% of all results falling within that range.

VIII   Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX   Conclusion:

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