March 15, 2024

Universal Biosensors Pty Ltd
Nick Bliesner
Head of Operations
Universal Biosensors Pty Ltd
1 Corporate Avenue, Rowville, Victoria, 3178,
Australia

Re: K230802
Trade/Device Name: Xprecia Prime Coagulation System
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS
Dated: March 15, 2023
Received: March 23, 2023

Dear Nick Bliesner:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software

Change to an Existing Device" (https://www.fda.gov/media/99785/download). Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems. For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230802

Device Name
Xprecia Prime™ Coagulation System

Indications for Use *(Describe)*
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.

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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510K Summary Document

Table of Contents

A. 510(k) Summary

This Document is the 510 (K) summary for Xprecia Prime™ Coagulation System

B. Purpose for Submission

New Device

C. Measurand

Prothrombin time in INR (International Normalized Ratio) and seconds

D. Type of Test

Electrochemical technology with amperometric detection of thrombin activity

E. Applicant:

Sponsor

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Primary 510(k) Contact:

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Dr Marcia L. Zucker

Regulatory Consultant (USA Contact)

Phone: 732-603-1194

E-mail: Mlzucker.zivd@gmail.com

F. Proprietary & Established Name:

Proprietary /Trade Name: Xprecia Prime™ Coagulation System

Established /Common name: Prothrombin time test

G. Regulatory Information:

G.1 Regulation section:

21 CFR 864.7750, Prothrombin time test

G.2 Classification:

Class II

G.3 Product code:

GJS, Test, time, prothrombin

G.4 Panel:

Haematology (81)

H. Intended 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.

I. Device Description

The Xprecia Prime™ Coagulation System has been specifically designed to monitor INR of patients undergoing anticoagulation therapy with warfarin (Vitamin K antagonist). It consists of the Xprecia Prime™ Coagulation Analyzer, Xprecia Prime™ PT/INR Test Strips and Xprecia™ Systems PT Controls.

The Xprecia Prime™ Coagulation 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 strip and the analyzer detects when clotting has occurred. The result is then displayed on the analyzer's screen in either units known as the International Normalized Ratio (INR) or in calibrated seconds.

J. Substantial Equivalence Information

Predicate device

- CoaguChek® XS System

Predicate device 510(k) number

- K060978

The Xprecia Prime™ Coagulation System is substantially equivalent to other products in commercial distribution intended for similar use.

Characteristics	***New Device Xprecia Prime™ Coagulation System***	***Predicate CoaguChek® XS System***
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 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.	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.
Measuring Range	0.8 to 8.0 INR	Same
Closed System	The Xprecia Prime™ Coagulation System, use Instrument and reagent strips that are provided by UBI and are intended to be used together.	The CoaguChek® XS System, use Instrument and reagent strips that are provided by Roche and are intended to be used together.
Specimen Type	Capillary whole blood	Capillary whole blood and non-anticoagulated venous whole blood
Minimum Sample Volume	8 µL	10 µL
Operating Principle/Technology	Electrochemical technology with amperometric (electric current) detection of thrombin activity	Same

Characteristics	*New Device* *Xprecia Prime™ Coagulation System*	*Predicate* *CoaguChek® XS System*
Test Strip Reagent	Human recombinant thromboplastin	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
Operating Temperature	15 °C to 32 °C (59 °F to 89 °F)	Same
Reference Range	INR: 0.9 to 1.1	Same
Test Strip Use Time	Within 10 minutes of removing from vial	Same
Hematocrit Range	Hematocrit range between 25 – 55 % do not significantly affect test results	Same
External Liquid Quality Control (LQC)	Liquid quality control in the normal and therapeutic range (Optional)	No external liquid quality control
Test Strip Stability	24 months	21 months
Memory	640 patient results 300 LQC results 300 system messages	300 test results with date & time
Heparin	Warfarin patient test results are unaffected by heparin concentrations up to 3 U/mL	Warfarin patient test results are unaffected by heparin concentrations up to 0.8 U/mL
Low Molecular Weight Heparin	Test is insensitive to low molecular weight heparin (LMWH) up to 3 IU anti-factor Xa activity/mL	Insensitive to low molecular weight heparins up to 2 IU anti factor Xa activity/mL.
Capillary Accuracy (All Sites)	Capillary blood on Xprecia Prime™ Coagulation System vs. venous plasma on a Sysmex® CS 2500 laboratory analyzer using Dade® Innovin® N=381 y= 1.10 x -0.1 Correlation: 0.97	Capillary blood on CoaguChek® XS vs. venous plasma on a Sysmex Analyzer using Dade Innovin (ISI = 1.02) N=700 y= 1 .006x + 0.032 Correlation: 0.971

K. Standard/Guidance Document Referenced (if applicable)

POCT 14 Point-of-care Coagulation Testing and Anticoagulation Monitoring, 2nd edition
CLSI GP41 – Collection of Diagnostic Venous Blood Specimens,7th edition
CLSI EP05-A3 – Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition.
CLSI EP09-c Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition.
CLSI EP07-A2 Interference Testing in Clinical Chemistry; Approved Guideline – Third Edition.
CLSI EP14-A3 Evaluation of Commutability of Processed Samples; Approved Guideline -Third Edition.
CLSI H47-A2 ne-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline - Second Edition.

L. Test Principle:

The Xprecia Prime™ Coagulation 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 strip and the analyzer detects when clotting has occurred. The result is then displayed on the analyzer's screen in either units known as the International Normalized Ratio (INR) or in calibrated seconds.

M. Performance Characteristics

M.1 Analytical Performance

M.1.1 Precision/Reproducibility

Intermediate Precision verification study on the Xprecia Prime™ Coagulation System as per CLSI EP05-A3 guidelines.

As per CLSI EP05-A3 guidelines, Intermediate precision studies were conducted as a laboratory (single site) over 20 days, with two runs per days each consisting of two replicates. Testing carried out on the Xprecia Prime™ Coagulation System passed the acceptance criteria of CV ≤5% for the 3 LQC's (across the range).

LQC Level	Mean INR	Repeatability SD	Repeatability CV (%)
Level 1	1.18	0.03	2.2
Level 2	2.81	0.03	1.0
Level 3	6.52	0.07	1.1

Reproducibility: Intermediate Precision: (5-day Study) External multisite reproducibility study was conducted using the Xprecia Prime™ Coagulation System with LQC material to access the precision of the system in the hands of untrained intended use operators (IUO)over a period of 5 days. as per the acceptance criteria CV ≤6%.

LQC Level	Mean INR	Repeatability SD	Repeatability CV (%)
Level 1	1.19	0.02	2.0
Level 2	2.62	0.03	1.3

Repeatability: Capillary repeatability for duplicate results from each enrolled subject demonstrated an overall CV < 5% across all sites and across the entire measuring range combined.

M.1.2 Linearity/assay reportable range:

A linearity study is not applicable to the Xprecia Prime™ Coagulation System

The assay reportable range (0.8 – 8.0 INR) of the Xprecia Prime™ Coagulation System was established through method comparison studies against the reference device (Sysmex® CS 2500 laboratory analyzer with Dade® Innovin® reagent).

M.1.3 Traceability, Stability, Expected values (control, calibrator, or methods)

M.1.3.1 Traceability

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

M.1.3.2 Xprecia Prime™ PT/INR Test Strips Stability

Real Stability: The stability of 24 months shelf life was established by storing three lots of Xprecia Prime™ PT/INR Test Strips at 5 +/- 3 ºC (41 ºF) & 30 +/- 2 ºC (86 ºF) and ambient to 75% Relative Humidity (RH) and testing using fresh whole blood and Liquid QC Samples.

In-Use Stability: In-use stability was tested to demonstrate that the Xprecia Prime™ PT/INR Test Strips can be kept outside the vial before measurement for up to 10 minutes at all operating temperatures.

Transport Stability: Xprecia Prime™ PT/INR Test Strips and packaging were validated by a transport stability study. The transport simulation requirements have been met and the product is appropriate for ambient shipping.

M.1.4 Detection Limit

The sensitivity to factors II, V, VII and X of the Xprecia Prime™ Coagulation System was performed by mixing varying amounts of factor II, V, VII and X deficient plasma, pooled normal plasma and red blood cells to final factor concentrations between 100% and 0%. These samples were then tested using nine Xprecia Prime ™ Coagulation Analyzers and three Xprecia Prime™ PT/INR Test Strips lots in each factor sensitivity study. The sensitivity of the Xprecia Prime™ Coagulation System to factors II, V, VII and X was estimated as 50%, 60%, 50% and 60%, respectively.

M.1.5 Analytical specificity Interference Limits:

Interference limits were established analyzing whole blood, obtained from normal subjects and patients on vitamin K antagonist (VKA) therapy, spiked separately with the interferents.

Interferent	Test Concentration
Acetaminophen	(Up to) 20 mg/L
Amoxicillin	(Up to)5.4 mg/dL
Apixaban	(Up to) 0.08 mg/L
Atorvastatin	(Up to) 96 mg/dL
Calcium Dobesilate	(Up to) 30 mg/L
Clexane	(Up to) 3 IU/mL
Cefitriaxone	(Up to) 84 mg/dL
Conjugated Bilirubin	(Up to) 40 mg/dL
Dabigatran	(Up to) 0.005 mg/L
Daptomycin	(Up to) 552 mg/L
Dexamethesone	(Up to) 12 mg/L
Edoxaban	(Up to) 0.06 mg/L
Ethinyl Estradiol	(Up to) 0.288 mg/L
Fondaparinux Sodium	(Up to) 5 mg/L
Hemoglobin	(Up to) 1000 mg/dL
Heparin	(Up to) 3300 U/L
Ibuprofen	(Up to) 219 mg/L
L-Ascorbic Acid	(Up to) 3 mg/dL
Lactate Dehydrogenase	(Up to) 250 U/L
Levonorgestrel	(Up to) 1.8 mg/L
Potassium Chloride	(Up to) 5 mmol/L
Prasugrel	(Up to) 72 mg/L
Prednisolone	(Up to) 3 mg/L
Protamine Sulfate	(Up to) 7.5 mg/L
Rivaroxaban	(Up to) 0.06 mg/L
Sodium Salicylate	(Up to) 0.0695 g/dL
Testosterone	(Up to) 480 mg/L
Ticagrelor	(Up to) 108 mg/L
Triglycerides	(Up to) 1500 mg/dL
Unconjugated Bilirubin	(Up to) 40 mg/dL
Uric Acid	(Up to) 24 mg/dL

Note: Anti-phospholipid (APA) and Lupus Anticoagulant (LA)

Anti-phospholipid (APA) and Lupus Anticoagulant (LA) positive patients may observe falsely prolonged INR values that do not reflect the exact degree of anti-coagulation on the Xprecia Prime™ Coagulation System. Where APA/LA is suspected to be present a PT/INR result should be confirmed on a laboratory-based APA/LA insensitive method.

M.1.6 Hematocrit:

The hematocrit range was evaluated for the Xprecia Prime™ Coagulation Analyzer using capillary blood samples from 371 patients across four intended use sites. Capillary blood samples for INR determinations using the Xprecia Prime™ Coagulation System, citrated plasma samples for the central laboratory INR using the Siemens Sysmex® CS-2500, and the measured EDTA venous whole blood hematocrit for each test subject were used in the analysis. The %bias of the Xprecia Prime™ Coagulation System INR to the Sysmex® CS-2500 INR was calculated for each test subject and plotted against the hematocrit for that test subject. Data analysis demonstrated that hematocrit range between 25 – 55% does not significantly affect test results.

M.1.7 Assay cut-off

Not Applicable

M.2 Comparison Studies

M.2.1 Method comparison with predicate Device CoaguChek®

Method Comparison Results for Xprecia Prime™ Coagulation System Vs Roche CoaguChek® -INR						
Matrix	N	Xprecia Prime™ Range	CoaguChek®	Slope (95%CI)	Intercept (95%CI)	(r)
Capillary	401	0.8-7.6	0.9-7.9	0.96 (0.939,0.985)	-0.01 (-0.083, 0.065)	0.97

Method Comparison Results for Xprecia Prime™ Coagulation System Vs Roche CoaguChek®-PT seconds						
Matrix	N	Xprecia Prime™ Range	CoaguChek®	Slope (95%CI)	Intercept (95%CI)	(r)
Capillary	401	9.7-91.6	10.5-96.0	0.962 (0.940,0.985)	-0.131 (-0.998,0.736)	0.97

Method Comparison with Reference device

A method comparison study was performed at 4 clinical sites in the US. The study showed:

Method Comparison Results for Xprecia Prime™ Coagulation System Vs Sysmex® CS-2500-INR					
N	Xprecia Prime™ Range	Sysmex® Range	Slope (95%CI)	Intercept (95%CI)	(r)
397	0.8-7.7	0.9-7.2	1.1 (1.073,1.117)	-0.12 (-0.183, -0.056)	0.98

Method Comparison Results for Xprecia Prime™ Coagulation System Vs Sysmex® CS-2500-PT seconds					
N	Xprecia Prime™ Range	Sysmex® Range	Slope (95%CI)	Intercept (95%CI)	(r)
397	9.7-95.5	9.55-72.6	1.307 (1.28,1.33)	-2.341 (-3.12, -1.56)	0.98

M.3 Clinical Studies

M.3.1.1 Clinical Sensitivity

Not applicable

M.3.1.2 Clinical Specificity

Not applicable

M.3.1.3 Other Clinical supportive data

Not applicable

M.4 Clinical Cut-Off

Not applicable

M.5 Expected Values/Reference range

Normal range testing was conducted on 120 patients who were not on oral anticoagulant therapy. Capillary samples were collected from each patient. Samples were tested on three lots of Xprecia Prime™ PT/INR Test Strips. Results demonstrated a normal range of 0.9 to 1.1 INR with more than 95% of all results falling within that range.

N. Instrument Name

Xprecia Prime™ Coagulation System

O. System Description

O.1 System Identification

The Xprecia Prime™ Coagulation System is a closed system, which is intended to be used exclusively with the Xprecia Prime™ PT/INR Test Strips manufactured by Universal Biosensors.

O.2 Specimen Sampling and Handling

Whole blood is manually applied to the target area of the test strip from top as a hanging drop of blood from the fingerstick (Capillary).

P. Calibration

P.1 Xprecia Prime™ PT/INR Test Strips:

Each lot of Xprecia Prime™ 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 Annex 6 Guidelines for thromboplastins and plasma used to control oral anticoagulant therapy with vitamin K antagonists (replacement of WHO Technical Report Series 889 Annex 3)

P.2 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. 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.

Q. Software

The user interface of the Xprecia Prime™ Coagulation Analyzer guides the user through the test procedure step by step. The user only needs to insert the strip and apply a blood sample. The Xprecia Prime™ Coagulation Analyzer measures International Normalized Ratio (INR) based on a Prothrombin Time (PT) assay and displays the result as seconds and INR. After the test is completed, the meter automatically saves the test result.

R. Cybersecurity

Cybersecurity evaluation and risk management documentation was prepared according to FDA Guidance Content of Premarket *Submissions for Management of Cybersecurity in Medical Devices*

(October 2, 2014) and *ANSI UL 2900-2-1, Standard for Safety, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems.*

S. Proposed Labeling

The Labeling is prepared as per the requirements of 21 CFR Part 809.10, *Labeling for in vitro diagnostic products*.

T. Conclusion

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