Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I 510(k) Number:

K183255

II Applicant:

CoaguSense, Inc.

III Proprietary and Established Names:

Coag-Sense Prothrombin Time (PT) / INR Monitoring Device

IV Regulatory Information:

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

V Submission/Device Overview:

A Purpose for Submission:

Modification of device(s) previously cleared for professional use under K050243 and patient self-testing under K093243. The hardware and operating system have been updated in the modified device.

B Measurand:

Prothrombin Time and International Normalized Ratio (INR)

C Type of Test:

Quantitative clotting assay

VI Intended Use/Indications for Use:

A Intended Use(s):

Same as Indication(s) for Use

B Indication(s) for Use:

Coag-Sense Prothrombin Time (PT) / INR Monitoring System (Professional Use)
The Coag-Sense Prothrombin Time (PT)/INR Monitoring System is an in vitro diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and INR units. It uses fresh capillary whole blood. It is intended for use by health care professionals at the point of care to monitor patients who are on warfarin-type (coumarin) anticoagulation therapy.

The device is not intended to be used for screening purposes.

Coag-Sense Prothrombin Time (PT) / INR Monitoring System (Self-Test)
The Coag-Sense Prothrombin Time (PT) / INR Monitoring System (Self-Test) is an in vitro diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and INR units. It uses fresh capillary whole blood. It is intended for use by properly selected and suitably trained patients or their caregivers on the order of the treating physician to monitor patients who are on anticoagulation therapy. Patients should be stabilized on warfarin-type (coumarin) anticoagulation therapy prior to self- testing.

The device is not intended to be used for screening purposes.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Not applicable

VII Device Description:

A Device Description:

The Coag-Sense Prothrombin Time (PT)/INR Monitoring System is a modification to the Immedia Prothrombin Time System cleared for professional use (K050243) and the Coag-Sense Prothrombin Time (PT)/INR Monitoring System cleared for patient self-testing (K093243). The hardware and operating system have been upgraded in the modified device to address parts and technology obsolescence, and to address current communications technologies. The modified Coag-Sense Prothrombin Time (PT)/INR Monitoring System uses the identical test strip, method of detection, thromboplastin reagent and calibration approach as found in the predicate system. The intended use and technological characteristics remain unchanged from that of the predicate

device. The new Coag-Sense Prothrombin Time (PT)/INR Monitoring System is available in two formats; one for Professional Use and one for Patient Self-Testing.

B Principle of Operation:

The Coag-Sense Prothrombin Time (PT)/INR Monitoring System measures the PT of fresh capillary whole blood using micro-mechanical end-point detection. The test is performed by inserting a test strip into the meter and applying a drop of blood to the sample receptacle of the test strip. The disposable test strip contains a rotating, spoked wheel that draws the sample into the reaction well after it is applied to the sample receptacle. The reaction well contains a pre-measured and dried quantity of thromboplastin. The wheel spokes rotate across the optical path of an infrared light beam. The spokes mix the patient sample with the reagent. As the patient sample transforms into a solid clot, it is picked up by the continuously-rotating spokes and is carried across the path of the infrared light beam interrupting the beam pattern. The time at which the clot interrupts the light beam is reported as the prothrombin time (PT). The PT seconds result is a true Prothrombin Time (patient's actual clotting time) and not a calculated value. The INR is calculated from the PT in seconds result, the Mean Normal Prothrombin Time (MNPT) and International Sensitivity Index (ISI) values for the reagent are determined by comparison to a WHO reference preparation.

C Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☒	☐
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   Coag-Sense Prothrombin Time (PT)/INR Monitoring System

2. Specimen Identification:

   Patient ID information must be scanned using the optional barcode scanner or manually entered in the meter when prompted.

3. Specimen Sampling and Handling:

   The Coag-Sense Prothrombin Time (PT)/INR test strip is intended for single-use only. Once the test strip is inserted into the meter, a drop of fresh capillary whole blood sample collected by fingerstick is manually applied to the test strip target area and analyzed by the Coag-Sense Prothrombin Time (PT)/INR meter.

4. Calibration:

The calibration parameters for each master lot of reagent is obtained during production by calibrating a subset of the test strips against a working International Reference Preparation (IRP) standard traceable to the tilt tube reference method adopted by the World Health Organization.

For each test strip lot, the calibration (MNPT and ISI) information used to convert PT in seconds to INR is conveyed to the meter on a lot specific Near Field Communication (NFC) tag, which is read using a built-in wireless NFC reader on the meter. This tag also contains strip lot expiration date and allowable low and high QC strip plasma clotting time ranges. The NFC Tag is located on the test strip box and is a micro data chip with antenna that contains the required test strip kit information. It allows transmission of the test strip kit information to the meter.

5. Quality Control:

High Control and Low Control Strips are provided for user quality control purposes and contain the same thromboplastin reagent as the patient test strips as well as plasma of known INR. The CoaguSense control strips form a clot using actual plasma of known INR and the identical lot of thromboplastin used in the manufacturing of the patient test strips. The process of running this liquid quality control tests the reagents' ability to generate a clot as well as the analyzer's ability to detect a clot. Control testing should be completed for each new lot of test strip received.

VIII Substantial Equivalence Information:

A Predicate Device Name(s):

Immedia Prothrombin Time System

Coag-Sense Prothrombin Time (PT)/INR Monitoring System

B Predicate 510(k) Number(s):

K050243

K093243

C Comparison with Predicate:

Device & Predicate Device(s):	**Subject Device** K183255	**Predicate Device** K050243 (Professional Use) K093243 (Self-Test Use)
Intended Use/Indications for Use	**Professional Use**	**Professional Use (K050243)**

Device & Predicate Device(s):	**Subject Device** K183255	**Predicate Device** K050243 (Professional Use) K093243 (Self-Test Use)
	The Coag-Sense Prothrombin Time (PT)/INR Monitoring System is an in vitro diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and INR units. It uses fresh capillary whole blood. It is intended for use by health care professional at the point of care to monitor patients who are on warfarin-type (coumarin) anticoagulation therapy. The Coag-Sense PT/INR System may be used for multiple-patient testing in a professional healthcare setting. The device is not intended to be used for screening purposes.	The Coag-Sense Prothrombin Time (PT)/INR Monitoring System is an in vitro diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and INR units. It uses fresh capillary whole blood. It is intended for use by health care professional at the point of care to monitor patients who are on warfarin-type (coumarin) anticoagulation therapy. The Coag-Sense PT/INR System may be used for multiple-patient testing in a professional healthcare setting. The device is not intended to be used for screening purposes.
	Self-Testing The Coag-Sense Prothrombin Time (PT)/INR Monitoring System (Self-Test) is an *in vitro* diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and INR units. It uses fresh capillary whole blood. It is intended for use by properly selected and suitably trained patients or their caregivers on the order of the treating physician to monitor patients who are on anticoagulation therapy. Patients should be stabilized on warfarin-type (coumarin) anticoagulation therapy prior to self-testing. The device is not intended to be used for screening purposes.	**Self-Testing (K093243)** The Coag-Sense Prothrombin Time (PT)/INR Monitoring System (Self-Test) is an *in vitro* diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and INR units. It uses fresh capillary whole blood. It is intended for use by properly selected and suitably trained patients or their caregivers on the order of the treating physician to monitor patients who are on anticoagulation therapy. Patients should be stabilized on warfarin-type (coumarin) anticoagulation therapy prior to self-testing. The device is not intended to be used for screening purposes.

Device & Predicate Device(s):	**Subject Device** K183255	**Predicate Device** K050243 (Professional Use) K093243 (Self-Test Use)
Test Principle	Rotating wheel physically lifts the clot at the time coagulation occurs and is detected by interruption of infrared light beam	Same
Clotting Reagent	Dried recombinant rabbit thromboplastin, stabilizers and preservatives	Same
Patient Test Strips	Disposable plastic strip with rotating wheel	Same
Blood Sample Size	10–12 µL	Same
Control Strips	Hi and Low-test control strips are provided with each carton of strips; each control strips contains plasma of known INR	Same
Quality Control	Internal self-check protocol to assure room temperature, timing functions, battery level and optical and mechanical functions are within specification	Same
Measurement Range	0.8 – 8.0 INR	Same
Hematocrit Range	15–60%	Same
Memory Capacity	• 2000 patient test results with date and time • 500 control test results with date and time • 1000 Operator accounts	100 tests with time, date, calibration code, controls and errors
PC and Printer Connectivity Method	Wired - Ethernet, USB Wireless - WiFi, Bluetooth	Wired - RS-232
Communications Port	USB	RS-232
User Interface Screen	Color LCD Touch Screen	Monochrome LCD display
Battery Type/Replaceable	Lithium Polymer battery. Not user replaceable	4 x 1.5V (AA) alkaline batteries. Replaceable by the user

IX Standards/Guidance Documents Referenced:

IEC 60601-1-2: 2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

CLSI POCT14-A: 2014 Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline

X Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   The precision of the Coag-Sense Prothrombin Time (PT)/INR Monitoring System was evaluated during the clearance of the device for professional use using control material, therapeutic samples (plasma and whole blood), and capillary whole blood. Refer to submission K050243 for the details of this study.

2. Linearity/Assay Reportable Range:

   The linear range of the Coag-Sense Prothrombin Time (PT)/INR Monitoring System was established during the clearance of the device for professional use. The system was found to be linear up to an INR of 8.0. Refer to submission K050243 for the details of the linearity study.

3. Analytical Specificity/Interference:

   An interference study was conducted to determine the level of interference with the INR results generated by the device for the following interfering substances: bilirubin, hemolysis, heparin, low molecular weight heparin, and lipemia. Refer to submission K050243 for the details of this study.

4. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Stability

   The stability of the Coag-Sense PT/INR test strips and the control test strips (high and low) were tested at designated time intervals, under varying storage conditions during the clearance of the device for professional use. Refer to submission K050243 for the details of this study.

   Traceability

   Each lot of Coag-Sense PT/INR test strips is factory calibrated to a reference lot of human recombinant thromboplastin traceable to the WHO International Reference Preparation, rTF/16.

5. Detection Limit:

   Detection limits for the Coag-Sense Prothrombin Time (PT)/INR Monitoring System were established during the clearance of the device for professional use. Refer to submission K050243 for the details of this study.

6. Assay Cut-Off:

Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

A study was conducted comparing the modified device to the predicate device at a single-site using whole blood from normal subjects not on oral anticoagulation therapy as well as from subjects on oral anticoagulation therapy. To validate the performance of the system across the measuring range, plasma samples ranging from 0.9 to 7.4 INR were also tested.

Test meters representing the predicate device (PT1) and the modified device (PT2) were paired in three sets (PT1 vs. PT2) analyzing identical test samples. The test samples included contrived plasma control samples covering medical decision levels of PT/INR measurements as well as whole blood samples from therapeutic patients and normal subjects (not on warfarin therapy). Plasma samples spanning the INR measuring range of the device (INR 0.9–7.4) were included in the study. Each test sample in this study was tested five times on each meter, for a total of 15 data points for PT1 and 15 data points for PT2.

In addition, whole blood samples were obtained from five different therapeutic patients and five different normal subjects. Three separate fingerstick samples were collected, each fingerstick providing two samples for each set of meters. Bland-Altman bias plots were created to evaluate agreement between the two quantitative measurements. The resulting graph shows the difference between the two paired measurements (PT1 -PT 2) plotted against the average of these measures ((PT1+PT2)/2). The analysis demonstrates that the acceptance criteria were met, and the modified device has acceptable bias across samples and INR ranges when compared to the predicate device.

Calibration Comparison: RTF/09 vs. RTF/16

During the clearance of the predicate device (PT1), reagents used in the test and control strips were calibrated against International Reference Preparation (IRP) rTF/09. Due to the phasing out of IRP rTF/09, reagents used in the test and control strips for the modified device (PT2) were calibrated to the current IRP rTF/16. To ensure that the change in IRP did not impact the performance of the modified device, an internal study was conducted to compare strip lots calibrated against rTF/09 against strip lots calibrated against rTF/16. Nine different plasma samples spanning the AMR were used in the study. The samples were tested on both PT1 and PT2 meters using test strips containing reagent that were calibrated using IRP rTF/09 and a current test strip lot containing reagents calibrated using IRP rTF/16. Linear regression and bias analysis demonstrate that the two lots of test strips, rTF/09 and rTF/16, correlate well with acceptable performance across the AMR, and that the modified PT2 meter performs the same as the predicate PT1 meter.

Comparison to Reference Method

Performance of the Coag-Sense PT/INR Monitoring System (modified device) was evaluated by comparison to the laboratory reference method. Customer conducted correlation studies were performed at six clinical sites using 12 POC operators. A fingerstick sample was

collected from each patient and the capillary whole blood was applied to the Coag-Sense test strip. A venous sample was collected at the same time and sent for testing on the plasma-based Diagnostica Stago analyzer. All Coag-Sense test strips used in these studies were calibrated against IRP rTF/16. A total of 203 patient samples were analyzed across the six sites, including INR values ranging between 0.9–5.1.

The pooled customer data was analyzed using regression analysis; the correlation coefficient (r), slope and intercept were determined for the data set, and graphs of the regression and bias analysis results were generated. The data demonstrate acceptable performance.

2. Matrix Comparison:

   Not applicable

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

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

   Usability Testing

   A usability study was conducted to verify changes in the user interface. To gain feedback on the general user interface flow and labeling materials, a formative evaluation was performed by 10 users unfamiliar with the use of home-use devices. The formative evaluation was followed by a summative validation study which was performed by two groups: 1) professional users and 2) home use patients. The professional user group included 10 users with some experience on the original Coag-Sense meter and five users who had familiarity with fingerstick point-of-care devices (n= 15 professional users). The study was performed at three sites for the professional group. The home use patient group included 20 users experienced with fingerstick testing at home and 10 inexperienced users, not familiar with home test monitoring devices (n= 30 home use patients).

   Once testing concluded, both groups of users were asked to complete a questionnaire to evaluate the ease of use for various features of the meter and the clarity of the instructions for use. All usability testing results were determined to be acceptable.

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

A normal range study was conducted on 120 healthy subjects not on anticoagulation therapy. The PT reference interval was established as 11.6–14.5 seconds and the INR range was established as 0.8–1.2 during the clearance of the device for professional use. Refer to submission K050243 for the details of this study.

F Other Supportive Instrument Performance Characteristics Data:

Validation and Verification

Validation and verification studies including bench testing, transportation testing, and electrical safety testing were performed on the modified Coag-Sense PT/INR Monitoring System. Bench testing included the following studies: *Viral Inactivation Study, Cleaning/Disinfection Study, Component Testing* (including power consumption, battery, clock, temperature, humidity, memory, and communication), *Drop Test,* and *Vibration Testing.* In addition, *Transit Testing* was conducted to demonstrate that the meter can withstand shipping simulation, including drop and shock conditions during transportation.

Electrical Safety Testing

Electrical safety testing was performed per the applicable sections of the following electrical safety standards:

- IEC 61010-1:2010; Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- IEC 61010-2-101:2015; Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Software Verification and Validation

Software verification and validation was performed on functions of the software to ensure that the software performs as intended. Verification and validation testing of the Coag-Sense PT/INR Monitoring System demonstrated that the software performed as intended and demonstrated acceptable performance. Cybersecurity documentation was prepared according to FDA Guidance Content of Premarket *Submissions for Management of Cybersecurity in Medical Devices (October 2, 2014).*

The verification and validation tests passed all predetermined acceptance criteria. The modified device met design input requirements, product specifications and relevant standards.

XI Proposed Labeling:

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

XII Conclusion:

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