

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k093243

B. Purpose for Submission:

To obtain clearance for home-use patient self-testing with the Immedia™ Prothrombin Time System previously cleared for professional use (k050243). The home use patient self-testing device is renamed as CoaguSense Self-Test Prothrombin Time/INR Monitoring System.

C. Measurand:

Prothrombin Time

D. Type of Test:

Quantitative clotting assay

E. Applicant:

CoaguSense, Inc.

F. Proprietary and Established Names:

CoaguSense Self-Test Prothrombin Time/INR Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR §864.7750 - Prothrombin Time Test
2. Classification:
Class II
3. Product code:
GJS - test, time, prothrombin
4. Panel:
81 Hematology

H. Intended Use:

1. Intended use(s):
The CoaguSense Self-Test PT Monitoring System is an *in vitro* diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and international normalized ratio (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 doctor. Patients should be stabilized on warfarin-type (coumarin) anticoagulation therapy prior to self-testing with the CoaguSense Self-Test PT Monitoring System. It is not intended to be used for screening purposes.
2. Indication(s) for use:
Same as Intended use.
3. Special conditions for use statement(s):
Prescription use only
4. Special instrument requirements:

I. Device Description:

CoaguSense Self-Test Prothrombin Time/INR Monitoring System is the identical device to the Immedia™ PT System, which was cleared for professional use under k050243.

This premarket notification is being submitted to obtain clearance for patient self-testing.

J. Substantial Equivalence Information:

1. Predicate device name(s):
 - Immedia™ Prothrombin Time System (Farallon Medical, Inc.)
2. Predicate 510(k) number(s):
 - k050243
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Measure prothrombin time	Same
Technology	Optical detection of light beam interruption by clot	Same
Reagent Supplies	Test Strip, Calibration Strip, High and Low Control Strips	Same

Differences		
Item	Device	Predicate
Indications	Home users	Professional use
Sample Transfer Device	Minipipette & PolyPet Sample Transfer Tubes	Minipipette

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

Points to Consider for Collection of Data in Support of In Vitro Device Submissions for 510(k) Clearance

510(k) Submission for Coagulation Instruments - Guidance for Industry and FDA Staff, June 19, 2003

Assessing the Safety and Effectiveness of Home-Use In Vitro Diagnostic Devices (IVDs): Draft Points to Consider Regarding Labeling and Premarket Submissions; CDRH Guidance, October 1988

CLSI H49-A, Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline

CLSI H47-A, One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline (1996)

CLSI H21-A5, Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays

L. Test Principle:

When a blood sample is applied to the application area of a test strip, the blood flows into the reaction area of the test strip where spokes on the rotating wheel mix the blood with recombinant rabbit thromboplastin, thereby starting the extrinsic coagulation pathway. As coagulation occurs, the formed clot is gathered by the

spokes and carried across a light beam. Interruption of the light beam is measured by an optical detector. The PT is reported as the time between the introduction of blood onto the test strip and blockage of the light beam, while the INR is calculated from the PT using the calibration parameters read from the test strip.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision of duplicates for capillary blood results was calculated from the 3-site method comparison study where the study subjects performed a duplicate self-test at the clinic in week 5 and week 10, and the healthcare professional (HCP) collected two fingerstick samples from the study subjects and performed the duplicate tests in week 3 and 7. Precision of test results was determined on each set of duplicates by calculating the mean and the confidence interval. The average CVs for both trained users and HCP are below the acceptance criteria of 6% and the results are summarized as follows:

	User results	Professional Results
N	226	225
INR Mean	2.48	2.55
INR Range	0.90 – 5.10	0.80 – 5.80
Mean CV	3.44	2.53
95% CI of CV's	2.79 – 4.10	2.12 – 2.94
Correlation (r)	0.96	0.98
Intercept	0.06	0.07
Slope	0.97	0.96

b. *Linearity/assay reportable range:*

Established under k050243

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

Established under k050243

d. *Detection limit:*

Established under k050243

e. *Analytical specificity:*

Established under k050243

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:* The study compared test results obtained by trained users to results obtained by healthcare professionals using the CoaguSense Self-Test PT Monitoring System. The patient performed a total of 15 self-testing at home over a period of 10 weeks, with 5 scheduled visits to their study site. After the initial visit, all study subjects provided duplicate test samples during clinic visits (weeks 3, 5, 7, 10). The subjects performed a duplicate self-test at the clinic in week 5 and week 10, and HCP collected two fingerstick samples from the study subjects and performed the duplicate tests in week 3 and 7. During each office visit, a venous reference sample (3.2% sodium citrate) was collected from each study subject and

analyzed with Diagnostica Stago STA Compact system using Dade[®] Innovin[®] thromboplastin reagent. A total of 117 subjects were enrolled, and 108 subjects completed all four visits. Comparing test results obtained by patients with results obtained by HCPs showed a correlation coefficient of 0.98 ($y = 1.03x - 0.08$, $n=546$). Comparing test results from the CoaguSense Self-Test PT Monitoring System with results from the laboratory reference method showed that the correlation coefficients were 0.91 for results by study subjects ($y = 0.91x + 0.08$, $n=538$) and 0.92 for results by HCP ($y = 0.92x + 0.18$, $n=541$).

- b. Matrix comparison:*
Not applicable.
3. Clinical studies:
 - a. Clinical Sensitivity and Specificity:*
Not applicable.
 - b. Other clinical supportive data (when a. is not applicable):*
Not applicable.
4. Clinical cut-off:
Not applicable.
5. Expected values/Reference range:
Please see original 510(k) submission (k050243).

N. Instrument Name:

CoaguSense PT/INR Meter

O. System Descriptions:

1. Modes of Operation:
Manual, closed system
2. Software:

All components of the device are controlled/monitored by software, which is responsible for the functionality, user interface, safety checks and performance accuracy.

The software controls the LCD screen, the 4-key keypad and the beeper for the user interface. It also controls the barcode reader for reading the information on the strips and the EEPROM for storing information.

For performing a patient test, a calibration or a control function, the software controls the following devices:

- A heater and thermistor for controlling the temperature of the sample
- An optical interrupter to determine when a strip is inserted
- An optical path for determining the existence of a clot in the sample
- An optical path for determining if the strip is correctly inserted, and whether it has a liquid sample applied
- A room temperature thermistor
- A motor and motor control for rotating the strip wheel

The software leads the user through the steps needed for each function, makes any needed calculations and displays the results.

The software also interfaces with a real time clock/sleep battery and a power supply for power management. The software also uses a RS232 interface for connecting to the Host Computer.

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

Yes or No

3. Specimen Identification:

Date and time of testing is recorded by the CoaguSense PT/INR Meter

4. Specimen Sampling and Handling:

Fresh capillary whole blood.

5. Calibration:

As established under k050243, CoaguSense Self-Test Prothrombin Time/INR Monitoring System is precalibrated. When the Calibration strip that is supplied with each carton of test strips is inserted into the meter the bar coded calibration information is entered. Strips from different test kits or an expired strip will generate an error message and will not allow the test to be run.

6. Quality Control:

As established under k050243, each carton of test strips contains 2 control strips (containing thromboplastin with low/high level of plasma) to be tested at start of each new carton of strips or when PT results are suspect.

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

- a. Electrical Safety Testing: The testing was performed by Underwriter's Laboratory (UL) and demonstrates the system complies with safety requirements for electrical equipment for measurement, control, and laboratory use as described in UL 61010-1, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use.
- b. Electromagnetic (EMC) Compatibility Testing: Testing is still in progress to ensure that the CoaguSense Self-Test PT Monitoring System complies with electromagnetic compatibility requirements of the medical EMC standards, IEC/EN 60601-1-2 for emissions and immunity of medical devices of the
- c. Environmental Testing: The CoaguSense Self-Test PT Monitoring System passed testing under the normal conditions of use: temperature range of 18°C - 32 °C and humidity range of 10% – 85% RH.
- d. Impact Testing: A drop test confirmed that the CoaguSense Self-Test PT Monitoring System meter provides accurate test results and does not shatter, crack or become damaged following multiple drops from countertop height

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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