February 21, 2019

CoaguSense, Inc.
Robin Bush
Director, Regulatory Affairs
48377 Fremont Blvd. Suite #113
Fremont, California 94538

Re: K183255
Trade/Device Name: Coag-Sense Prothrombin Time (PT) / INR Monitoring Device
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS
Dated: November 19, 2018
Received: November 21, 2018

Dear Robin Bush:

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. 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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183255

Device Name
Coag-Sense Prothrombin Time (PT) / INR Monitoring System (Professional Use)

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Appendix S

Date of Summary

December 20, 2018

Type of Submission

Traditional 510(k)

510(k) Applicant

CoaguSense Inc.
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Phone: 510-270-5442

Primary Contact

Robin Bush
Director, Regulatory Affairs
510-270-5442
Email: rbush@coagusense.com

Device Overview

Trade Name:	Coag-Sense Prothrombin Time (PT)/INR Monitoring System
Common Name:	PT/INR Test System
Classification Name:	Prothrombin Time Test
Regulation Number:	§864.7750
Product Code:	GJS

Predicate Device

The predicate devices for this premarket submission:

Trade Name	510(k) Submitter	510(k) Number
Coag-Sense Prothrombin Time (PT)/INR System (Professional Use)	Farallon Medical (CoaguSense Inc.)	K050243
Coag-Sense Prothrombin Time (PT)/INR System (Patient Self-Testing)	CoaguSense Inc.	K093243

Device Description

The Coag-Sense Prothrombin Time (PT)/INR Monitoring System is a portable medical device for the measurement of the Prothrombin Time (PT) using fresh capillary whole blood obtained from a finger stick. The Coag-Sense Prothrombin Time (PT)/INR Monitoring System is a hand held device and directly detects clot formation. The 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 disposable test strip. The test strip contains a rotating, spoked wheel that draws the sample into the reaction well after it is applied to the sample receptacle. The spokes rotate across the path of an infrared light beam and mix the liquid sample with the thromboplastin which is dried in the reaction well. When the sample clots, the clot is picked up by the spokes, interrupting the path of the infrared light beam that is detected by the meter.

The PT test and the result is displayed as International Normalized Ratio (INR) and seconds (PT). The result is date/time stamped and stored in the memory of the meter.

The device is powered by batteries and/or AC adapter. This PT/INR System uses the exact same test and control strip as the predicate devices.

Intended Use / Indications for Use

The same meter and test strip is used for both professional and self-test (home) use.

For professional users, 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 device is not intended to be used for screening purposes.

For self-test users, 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.

The device 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.

Performance Data

Bench testing, transportation testing, electrical safety testing was performed on the modified Coag-Sense PT/INR Monitoring System, demonstrating that it met the pre-determined acceptance criteria and design specifications.

- Bench Testing

  The following bench tests were performed:

  - Viral Inactivation Study
  - Cleaning/Disinfection Study
  - Component Testing (including power consumption, battery, clock, temperature, humidity, memory, communication)
  - Drop Test
  - Vibration Testing
  - Transit Testing

- Electrical Safety Testing

  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

Cybersecurity documentation was prepared according to FDA Guidance Content of Premarket *Submissions for Management of Cybersecurity in Medical Devices (October 2, 2014)*.

Software Verification and Validation

Software verification and validation was performed on the 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 the software performed as intended, met acceptance criteria, and does not have a negative impact on product performance or product safety.

Usablity Testing

A usability study was conducted according to EN 62366 and FDA guidance to verify the changes in user interface. All users agreed or strongly agreed that the navigation features were easy to use. 100% of professional users and 97% of self-test users strongly agree that overall, the modified Coag-Sense meter is satisfactory.

All testing results met the pre-determined acceptance criteria that were established in the test protocols. Based on the testing, the Coag-Sense PT/INR Monitoring System performs as intended, with no new questions of safety or effectiveness identified during testing.

Testing In Support Of Substantial Equivalence Determination

The design verification testing and design validation testing performed on the modified meter demonstrate the subject device meets defined product specification and intended use. The testing demonstrates that the subject device has comparable performance to the predicate device. The bench testing performed verifies that the subject Coag-Sense PT/INR Monitoring System meets the specified performance specifications and thus, is substantially equivalent to the predicate device for professional and home use.

Comparison of Strip Lots

Comparative studies were performed using Coag-Sense strip lots calibrated against various standard laboratory tests. The studies confirmed Coag-Sensetest strips correlate extremely well, with no evidence of any bias across the AMR.

Comparison to Predicate Device

A side by side comparison study was performed with identical test samples to demonstrate that the performance of the modified Coag-Sense PT/INR meter is equivalent or better than the currently marketed predicate Coag-Sense PT/INR meter. Performance testing confirmed no difference in the results obtained on the modified meter when compared to the predicate device.

The subject Coag-Sense Prothrombin Time (PT)/INR Monitoring System is substantially equivalent to the cleared predicate (#K050243 and #K093243) with respect to indications for use, intended use, and technological characteristics.

The differences between the subject device and the predicate devices do not raise any new or different issues of safety and effectiveness. Design verification testing confirmed that no new questions of safety or effectiveness were identified during testing, and that the subject Coag-Sense PT/INR Monitoring System performs as intended.

Conclusion

Based on the comparative analysis, when considering the intended use, principles of operation, performance characteristics and technological characteristics, the Coag-Sense Prothrombin Time (PT)/INR Monitoring System does not introduce any new questions of safety and effectiveness. The minor differences between the subject Coag-Sense Prothrombin Time (PT)/INR Monitoring System and the predicate device raise no new issues of safety or effectiveness. Therefore, the Coag-Sense Prothrombin Time (PT)/INR Monitoring System is substantially equivalent to the predicate devices.