October 5, 2022

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

Re: K212779
Trade/Device Name: Coag-Sense Prothrombin Time (PT) / INR Monitoring System for Patient Self-Testing
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS
Dated: September 20, 2022
Received: September 01, 2021

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/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 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 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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212779

Device Name
Coag-Sense Prothrombin (PT) / INR Monitoring System for Patient Self-Testing

Indications for Use *(Describe)*

The Coag-Sense Prothrombin Time (PT) / INR Monitoring System for Patient Self-Testing is an in vitro diagnostic device that provides quantitative prothrombin time (PT) results, expressed in INR units. It uses fresh capillary whole blood.

The Coag-Sense Prothrombin Time (PT) / INR Monitoring System for Patient Self-Testing 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 Coag-Sense Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing is not intended to be used for screening purposes.

The Coag-Sense Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing is intended to be used by a single person and should not be shared.

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 2

Date of Summary

September 28, 2022

Type of Submission

Special 510(k)

510(k) Applicant

CoaguSense Inc.
48377 Fremont Blvd, Suite 113
Fremont CA, 94538
Phone: 510-892-2379

Primary Contact

Robin Bush
Consulting Director, Regulatory Affairs
510-908-5716
Email: rbushconsulting@earthlink.net

Device Overview

Trade Name:	Coag-Sense Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing
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 For Patient Self-Testing	CoaguSense Inc.	K183255

Device Description

The Coag-Sense Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing 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 for Patient Self-Testing is a handheld device that 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). The result is date/time stamped and stored in the memory of the meter.

The device is powered by 4 AA batteries. This Coag-Sense Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing uses the exact same test and control strip as the predicate devices.

Intended Use / Indications for Use

The Coag-Sense® Prothrombin Time (PT) / INR Monitoring System for Patient Self-Testing is an *in vitro* diagnostic device that provides quantitative prothrombin time (PT) results, expressed in INR units. It uses fresh capillary whole blood.

The Coag-Sense® Prothrombin Time (PT) / INR Monitoring System for Patient Self-Testing 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 Coag-Sense Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing is not intended to be used for screening purposes.

The Coag-Sense® Prothrombin Time (PT) / INR Monitoring System for Self-Testing is intended to be used by a single person and should not be shared.

Performance Data

This special 510(k) describes modifications to the user interface access (buttons to navigate the flow, compared to touchscreen in the predicate device). Functional bench testing, electrical safety and EMC testing was performed on the modified Coag-Sense Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing, demonstrating that it met the pre-determined acceptance criteria and design specifications.

- Functional Testing

  The following functional bench tests were performed:

  - Component Testing (including power consumption, battery, clock, temperature, humidity, memory, communication)
  - Drop Test
  - Vibration Testing
  - Transit Testing (Bulk)

- Electrical Safety / Electromagnetic Compatibility Testing

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

  - IEC 61010-1:2017; Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
  - IEC 61010-2-101:2018; Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
  - IEC 60606-1-2:2014, edition 4.1, 2020-09; Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

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.*

The risk analysis concludes that the Coag-Sense Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing has no significant detectable cybersecurity risks and has an acceptable overall risk.

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

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 Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing 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 IEC 62366-1 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 and self-test users strongly agree or agree that overall, the set-up and display on the modified Coag-Sense meter is easy to use.

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 functional bench testing performed verifies that the subject Coag-Sense Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing meets the specified performance specifications and thus, is substantially equivalent to the predicate device for home use.

Comparison to Predicate Device

No changes have been made in the test strips or chemistry. The mechanism of action to detect a clot remains the same. A side-by-side comparison study was performed with identical test samples to demonstrate that the performance of the modified Coag-Sense Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing is equivalent 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 for Patient Self-Testing is substantially equivalent to the cleared predicate (#K183255) with respect to indications for use for patient self-testing, 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 and side by side performance testing confirmed that no new questions of safety or effectiveness were identified during testing, and that the subject Coag-Sense Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing performs as intended.

Conclusion

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