January 04, 2023

Sienco, Inc.
Jennifer Aiken
Regulatory Compliance Director
5721 Arapahoe Ave, Unit A1-A
Boulder, Colorado 80303

Re: K223635
Trade/Device Name: Sonoclot Coagulation & Platelet Function Analyzer System with Sonoclot Viewer
Regulation Number: 21 CFR 864.7140
Regulation Name: Activated Whole Blood Clotting Time Tests
Regulatory Class: Class II
Product Code: JBP
Dated: November 30, 2022
Received: December 5, 2022

Dear Jennifer Aiken:

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 -S

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.

Submission Number *(if known)*

K223635

Device Name

Sonoclot Coagulation & Platelet Function Analyzer System with Sonoclot Viewer

Indications for Use *(Describe)*

The Sonoclot Coagulation & Platelet Function Analyzer System is an in vitro diagnostic device for measuring coagulation and platelet function. This system has two configurations. The historic configuration is a Sonoclot Analyzer connected to a thermal graphics printer. The standard configuration is a Sonoclot Analyzer connected to a computer running Sonoclot Viewer data collection software.

The Sonoclot Analyzer System rapidly provides information on the entire hemostasis process including coagulation, fibrin gel formation, clot retraction (platelet function) and fibrinolysis.

The Sonoclot Analyzer System generates a qualitative graph, known a the Sonoclot Signature, and quantitative results on the clot formation time (Activated Clotting Time-Onset), the rate of fibrin polymerization (Clot Rate), and clot retraction (Platelet Function). This information can be used to identify numerous coagulopathies including platelet dysfunction, factor deficiencies, anticoagulant effect, hypercoagulable tendencies and hyperfibrinolysis. Different disposable tests are available for use with the Sonoclot Analyzer System for different applications.

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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510(K) Summary: K223635

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Sienco, Inc.
Applicant Address	5721 Arapahoe Ave, Unit A1-A Boulder CO 80303 United States
Applicant Contact Telephone	303-420-1148
Applicant Contact	Ms. Jennifer Aiken
Applicant Contact Email	jenn@sienco.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Sonoclot Coagulation & Platelet Function Analyzer System with Sonoclot Viewer
Common Name	Activated whole blood clotting time tests
Classification Name	Activated Whole Blood Clotting Time
Regulation Number	864.7140
Product Code	JBP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary predicate is listed first)	Product Code
K002528	Sonoclot Coagulation & Platelet Function Analyzer System with Signature Viewer Option	JBP
K952560	Sonoclot Coagulation & Platelet Function Analyzer	JPA

Device Description Summary

21 CFR 807.92(a)(4)

The Sonoclot Coagulation & Platelet Function Analyzer System is an in vitro diagnostic device for measuring coagulation and platelet function. This system has two configurations. The historic configuration is a Sonoclot Analyzer connected to a thermal graphics printer. The standard configuration is a Sonoclot Analyzer connected to a computer running Sonoclot Viewer data collection software.

The Sonoclot Analyzer System rapidly provides information on the entire hemostasis process including coagulation, fibrin gel formation, clot retraction (platelet function) and fibrinolysis.

The Sonoclot Analyzer System generates a qualitative graph, known as the Sonoclot Signature, and quantitative results on the clot formation time (Activated Clotting Time-Onset), the rate of fibrin polymerization (Clot Rate), and clot retraction (Platelet Function). This information can be used to identify numerous coagulopathies including platelet dysfunction, factor deficiencies, anticoagulant effect, hypercoagulable tendencies and hyperfibrinolysis. Different disposable tests are available for use with the Sonoclot Analyzer System for different applications.

Sonoclot Viewer is a data collection, storage, and retrieval program for use with Sonoclot Analyzers. Sonoclot Viewer collects serial data from one or more Sonoclot Analyzers. This data is compressed, processed for certain performance results, displayed, and stored as data files.

Sonoclot Viewer enables users to assign patient, operator, and reagent information to a test, manage patient test results and analyzer/reagent quality control data, communicate with the hospital information system, and create reports to meet billing or regulatory compliance requirements.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Sonoclot Coagulation & Platelet Function Analyzer System is an in vitro diagnostic device for measuring coagulation and platelet function. This system has two configurations. The historic configuration is a Sonoclot Analyzer connected to a thermal graphics printer. The standard configuration is a Sonoclot Analyzer connected to a computer running Sonoclot Viewer data collection software.

The Sonoclot Analyzer System rapidly provides information on the entire hemostasis process including coagulation, fibrin gel formation, clot retraction (platelet function) and fibrinolysis.

The Sonoclot Analyzer System generates a qualitative graph, known a the Sonoclot Signature, and quantitative results on the clot formation time (Activated Clotting Time-Onset), the rate of fibrin polymerization (Clot Rate), and clot retraction (Platelet Function). This information can be used to identify numerous coagulopathies including platelet dysfunction, factor deficiencies, anticoagulant effect, hypercoagulable tendencies and hyperfibrinolysis. Different disposable tests are available for use with the Sonoclot Analyzer System for different applications.

Indications for Use Comparison

21 CFR 807.92(a)(5)

There are no changes to the indications for use from the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The Sonoclot Coagulation & Platelet Function Analyzer System with Sonoclot Viewer has the same technological characteristics as the predicate device, Sonoclot Coagulation & Platelet Function Analyzer System with Signature Viewer Option.

Sonoclot Analyzer model DP-2951 is the same analyzer model used in 510(k) K002528.

System configuration, comprised of Sonoclot Analyzer connected to a user provided computer running data collection software via serial to USB connection, is the same as the system configuration in 510(k) K002528.

There is no change in the information provided by the software. Sonoclot Viewer and Signature Viewer both provide a qualitative Sonoclot Signature graph and quantitative results for activated clotting time (ACT), rate of fibrin polymerization (Clot Rate), and platelet function information.

Non-Clinical and/or Clinical Test Summary & Conclusions

21 CFR 807.92(b)

Sonoclot Viewer is a reengineered software revision of the previously cleared software program, Signature Viewer, for use with Sonoclot Analyzers. These software programs have the same intended use, software features, and results calculations. Data filtering in Sonoclot Viewer has been improved to better analyze data that Signature Viewer could not analyze for quantitative results. Validation was performed to ensure that the results calculated by Sonoclot Viewer are equivalent to those calculated by the predicate software Signature Viewer. This validation used raw data collected in Signature Viewer, analyzed this data using the results calculation algorithms in Sonoclot Viewer, and compared the results generated by Sonoclot Viewer to the originally calculated Signature Viewer results. Results validation demonstrated that results calculated by Sonoclot Viewer are substantially equivalent to those calculated by the predicate software, Signature Viewer.