August 24, 2023

HemoSonics, LLC
Debbie Winegar
Vice-President, Clinical Affairs
4020 Stirrup Creek Drive, Suite 105
Durham, North Carolina 27703

Re: K232215
Trade/Device Name: Quantra Hemostasis Analyzer
Regulation Number: 21 CFR 864.5430
Regulation Name: Coagulation system for the measurement of whole blood viscoelastic properties in perioperative patients
Regulatory Class: Class II
Product Code: QFR
Dated: July 26, 2023
Received: July 26, 2023

Dear Debbie Winegar:

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, Ph.D.
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)*
K232215

Device Name
Quantra Hemostasis Analyzer

Indications for Use *(Describe)*
The Quantra® System is composed of the Quantra Hemostasis Analyzer, QPlus Cartridge, QStat Cartridge, and Quantra Quality Controls Level 1 and 2. The Quantra System is intended for in vitro diagnostic use.

The Quantra Hemostasis Analyzer uses Sonic Estimation of Elasticity via Resonance (SEER) Sonorheometry, an ultrasound-based technology, to measure the shear modulus of whole blood during coagulation. The system is intended to be used by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood.

The QPlus Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation state of a 3.2% citrated venous or arterial whole blood sample. The QPlus Cartridge includes tests to assess coagulation characteristics via the intrinsic pathway, via the extrinsic pathway, and includes tests with a heparin neutralizer. The QPlus Cartridge is indicated for use in cardiovascular or major orthopedic surgeries before, during, and following the procedure.

The QStat Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation and clot lysis state of a 3.2% citrated venous whole blood sample. The QStat Cartridge includes tests to assess coagulation characteristics via the intrinsic pathway, via the extrinsic pathway, and includes a test with tranexamic acid to evaluate clot lysis characteristics. The QStat Cartridge is indicated for use in trauma and liver transplantation procedures.

The Quantra System is indicated for the evaluation of blood coagulation in perioperative patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions. Results obtained with the Quantra System should not be the sole basis for patient diagnosis.

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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510(K) SUMMARY

A. APPLICANT INFORMATION

Submission Date: July 26, 2023

Submitter Information: HemoSonics, LLC
4020 Stirrup Creek Drive, Suite 105
Durham, NC 27703
Phone: 919-244-6990

Contact Person: Deborah Winegar, PhD
Email: dwinegar@hemosonics.com
Phone: 919-244-6990

B. PROPRIETARY AND ESTABLISHED NAMES

Quantra® Plus System, Quantra Hemostasis Analyzer, Quantra QPlus Cartridge

C. REGULATORY INFORMATION

Trade/Device Name:	Quantra QPlus System
Regulation Number:	21 CFR 864.5430
Regulation Name:	Coagulation system for the measurement of whole blood viscoelastic properties in perioperative patients
Regulatory Classification:	Class II
Product Code:	QFR

D. PURPOSE OF SUBMISSION

To implement a software modification to the Quantra Hemostasis Analyzer that will extend the QPlus Cartridge maximum assay time for reporting clot stiffness results from 15 minutes to 25 minutes. This change does not affect the device's intended use nor alter the device's fundamental scientific technology. There were no changes to the reagents, algorithms used to calculate results, reportable ranges of the output parameters, user interface, or results display.

E. MEASURAND

The combination of clot time and clot stiffness parameters measured from the four channels of the cartridge provides information about the functional role of coagulation factors, fibrinogen, and platelets in the sample.

F. TYPE OF TEST

The Quantra QPlus System is an in vitro diagnostic device designed to assess a patient's coagulation system by measuring the viscoelastic properties of a blood sample during clot formation.

G. INTENDED USE AND INDICATIONS FOR USE STATEMENT

The intended use/indications for use have not been modified from the intended use/indications for use cleared in K230461.

The Quantra® System is composed of the Quantra Hemostasis Analyzer, QPlus Cartridge, QStat Cartridge, and Quantra Quality Controls Level 1 and 2. The Quantra System is intended for in vitro diagnostic use.

The Quantra Hemostasis Analyzer uses Sonic Estimation of Elasticity via Resonance (SEER) Sonorheometry, an ultrasound-based technology, to measure the shear modulus of whole blood during coagulation. The system is intended to be used by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood.

The QPlus Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation state of a 3.2% citrated venous or arterial whole blood sample. The QPlus Cartridge includes tests to assess coagulation characteristics via the intrinsic pathway, via the extrinsic pathway, and includes tests with a heparin neutralizer. The QPlus Cartridge is indicated for use in cardiovascular or major orthopedic surgeries before, during, and following the procedure.

The QStat Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation and clot lysis state of a 3.2% citrated venous whole blood sample. The QStat Cartridge includes tests to assess coagulation characteristics via the intrinsic pathway, via the extrinsic pathway, and includes a test with tranexamic acid to evaluate clot lysis characteristics. The QStat Cartridge is indicated for use in trauma and liver transplantation procedures.

The Quantra System is indicated for the evaluation of blood coagulation in perioperative patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions. Results obtained with the Quantra System should not be the sole basis for patient diagnosis.

H. DEVICE MODIFICATION DESCRIPTION

HemoSonics is submitting this Special 510(k) to implement a software modification to the Quantra Hemostasis Analyzer that will extend the QPlus Cartridge maximum assay time for reporting clot stiffness results from 15 minutes to 25 minutes.

I. SUBSTANTIAL EQUIVALENCE INFORMATION

Predicate Device Name: Quantra QPlus System

Predicate 510(k) Number: K230461

Comparison with the Predicate:

Table 7-1 provides an overall comparison of the modified Quantra System with the previously cleared Quantra System.

Table 7-1: Comparison between the Modified Quantra Hemostasis Analyzer and QPlus Cartridge and the Predicate Device (K230461)

	Modified Device	**Predicate Device**
	Quantra Hemostasis Analyzer and QPlus Cartridge (Subject of Special 510(k))	**Quantra Hemostasis Analyzer and QPlus Cartridge (K230461)**
Similarities		
Manufacturer	Same as predicate	HemoSonics, LLC
Trade Name	Same as predicate	Quantra Hemostasis Analyzer
Common Name	Same as predicate	Whole Blood Hemostasis System
Classification Name	Same as predicate	Coagulation system for the measurement of whole blood viscoelastic properties in perioperative patients
Regulation Number	Same as predicate	21 CFR 864.5430
Product Code	Same as predicate	QFR
Device Class	Same as predicate	II
Location of Use	Same as predicate	Point of care and laboratory settings
Disposables	Same as predicate	QPlus Cartridge (multichannel cartridge) Quantra Quality Controls (Level 1 and Level 2)
Analyzer Hardware	Same as predicate	Quantra Hemostasis Analyzer HS-002
Indications for use	Same as predicate	The Quantra Hemostasis Analyzer is an automated in vitro diagnostic device intended to provide indications of the coagulation state of a patient's whole blood sample. The Quantra uses SEER Sonorheometry to measure the kinetic changes as the sample clots in real time. The Quantra output consists of numerical values for clot time and clot stiffness-based coagulation parameters. Quantra is for use by professionals at the point of care or in a laboratory setting. The QPlus Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation state of a 3.2% citrated venous or arterial whole blood sample. The QPlus Cartridge includes tests to assess coagulation

	Modified Device	Predicate Device
	Quantra Hemostasis Analyzer and QPlus Cartridge (Subject of Special 510(k))	**Quantra Hemostasis Analyzer and QPlus Cartridge (K230461)**
		characteristics via the intrinsic and extrinsic pathways and includes tests with a heparin neutralizer. The QPlus Cartridge is intended for *in vitro* diagnostic use by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood by means of the following functional parameters: Clot Time (CT), Clot Time with Heparinase (CTH), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Clot Time Ratio (CTR), and Platelet Contribution to Clot Stiffness (PCS). The QPlus Cartridge is indicated for the evaluation of blood coagulation in perioperative patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in cardiovascular or major orthopedic surgeries before, during, and following the procedure. Results obtained with the QPlus Cartridge should not be the sole basis for patient diagnosis. For prescription use only.
Intended Use	Same as predicate	Same as Indications for Use
Sample Type(s)	Same as predicate	Arterial and venous whole blood
Microsoft Windows Operating System	Same as predicate	Windows 10 IoT Enterprise LTSC
Maximum assay time for QPlus Cartridge for calculating CT, CTH, CTR results	Same as predicate	15 minutes from test initiation
Differences		
Analyzer Software	V2.4.1	V2.2.16
Maximum assay time for QPlus Cartridge for calculating CS, PCS, FCS results	25 minutes from test initiation	15 minutes from test initiation

J. CLINICAL AND NON-CLINICAL STUDIES

The following studies were conducted to support this modification:

Interfering Substance Testing
The interference study tested substances for which "Not Computable" results due to delayed clot initiation were reported for CS and/or FCS in the studies conducted in support of DEN180017. For testing the modified device, similar protocols, acceptance criteria, and sample sizes were utilized. As only the direct-acting oral anticoagulants dabigatran and rivaroxaban generated results reported as "Not Computable" due to delayed clot initiation for CS and/or FCS, testing was limited to these two agents. As previously observed, rivaroxaban and dabigatran demonstrated a dose response effect of clot time parameter prolongation (starting at 100 ng/mL and at all levels tested, ≥ 25 ng/mL, respectively) and clot stiffness parameter reduction (starting at 200 and 100 ng/mL respectively).

Precision Testing: Whole Blood Repeatability Study
The precision study evaluated whole blood repeatability and assessed the precision of the modified device using whole blood samples across multiple instruments, operators, and cartridge lots. This whole blood repeatability study was performed with contrived whole blood requiring an assay time within the extended maximum assay time. Total imprecision, including variability between operators, cartridge lots, instruments, and test replicates ranged from 5.8% to 14.4% CV.

Clinical Performance Testing
Clinical samples were collected from adult cardiac surgery patients undergoing treatment in the intensive care unit at a single medical center. It was expected that this segment of the intended use population would enrich the sample set with samples expected to have delayed clot initiation.

Samples were analyzed on the modified Quantra System with the QPlus Cartridge in parallel with testing on the ROTEM delta *(Werfen, Bedford, MA)*. Correlation analyses were performed to compare measurements obtained with the QPlus Cartridge to comparable measurements obtained with the ROTEM delta CT vs INTEM CT, CS vs EXTEM A20, FCS vs FIBTEM A20 and PCS vs PLATEM (defined as EXTEM A20 - FIBTEM A20).

Linear regression summary results for all comparisons showed $r > 0.8$ (0.82 to 0.94) for the correlation analysis, demonstrating a strong correlation of QPlus parameters to corresponding ROTEM delta parameters.

K. CONCLUSION

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