March 24, 2023

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

Re: K230461
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: February 21, 2023
Received: February 21, 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)*
K230461

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5: 510(K) SUMMARY

A. APPLICANT INFORMATION

Submission Date: February 21, 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® System

C. REGULATORY INFORMATION

Trade/Device Name:	Quantra 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 new operating system (Microsoft Windows 10 IoT Enterprise LTSC 2019) in the Quantra Hemostasis Analyzer. This change does not affect the device's intended use nor alter the device's fundamental scientific technology.

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 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 and

lysis in trauma, surgical and intensive care settings. The system consists of the Quantra Hemostasis Analyzer (instrument), single-use disposable cartridges, (QPlus and QStat cartridges) and Quantra Quality Controls (external Quality Control materials).

G. INTENDED USE/INDICATIONS FOR USE

The intended use/indications for use have not been modified from the intended use/indication for use cleared in K213917 and K223433.

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 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 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 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 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. The QPlus Cartridge is indicated for use in cardiovascular or major orthopedic surgeries before, during, and following the procedure. The QStat Cartridge is indicated for use in trauma and liver transplantation procedures.

Results obtained with the Quantra System should not be the sole basis for patient diagnosis.

H. DEVICE MODIFICATION DESCRIPTION

The Quantra System was previously cleared under K213917 and K223433. HemoSonics is submitting this Special 510(k) to implement a new operating system (W10IoT) in the Quantra Hemostasis Analyzer.

SUBSTANTIAL EQUIVALENCE INFORMATION

Predicate Device Name: Quantra System

Predicate 510(k) Number: K223433, K213917

Comparison with the Predicate:

Table 5-1 provides an overall comparison of the modified Quantra System with the previously cleared Quantra System.

Table 5-1: Comparison between Quantra System (K223433, K213917) and Modified Quantra System

	Modified Device	**Predicate Device**
	Quantra System (Subject of Special 510(k))	**Quantra System (K223433, K213917)**
Similarities		
Manufacturer	Same as predicate device	HemoSonics, LLC
Trade Name	Same as predicate device	Quantra Hemostasis Analyzer
Common Name	Same as predicate device	Whole Blood Hemostasis System
Classification Name	Same as predicate device	Coagulation system for the measurement of whole blood viscoelastic properties in perioperative patients.
Regulation Number	Same as predicate device	21 CFR 864.5430
Product Code	Same as predicate device	QFR (K213917, K223433)
Device Class	Same as predicate device	II
Indications for Use	Same as predicate device	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

	Modified Device	Predicate Device
	Quantra System (Subject of Special 510(k))	**Quantra System (K223433, K213917)**
		tranexamic acid to evaluate clot lysis characteristics. The QStat Cartridge is indicated for use in trauma and liver transplantation procedures. 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.
Intended Use	Same as predicate device	Same as indications for use
Disposables	Same as predicate device	QPlus Cartridge (multichannel cartridge) QStat Cartridge (multichannel cartridge) Quantra Quality Controls (Level 1 and Level 2)
Analyzer Hardware	Same as predicate device	Quantra Hemostasis Analyzer HS-002
Differences		
Quantra Hemostasis Analyzer Software	v2.2.16	v2.0.36.1 (K213917) v2.1.37 (K223433)
Embedded Windows Operating System	Microsoft Windows 10 IoT Enterprise LTSC 2019	Windows Embedded Standard 8